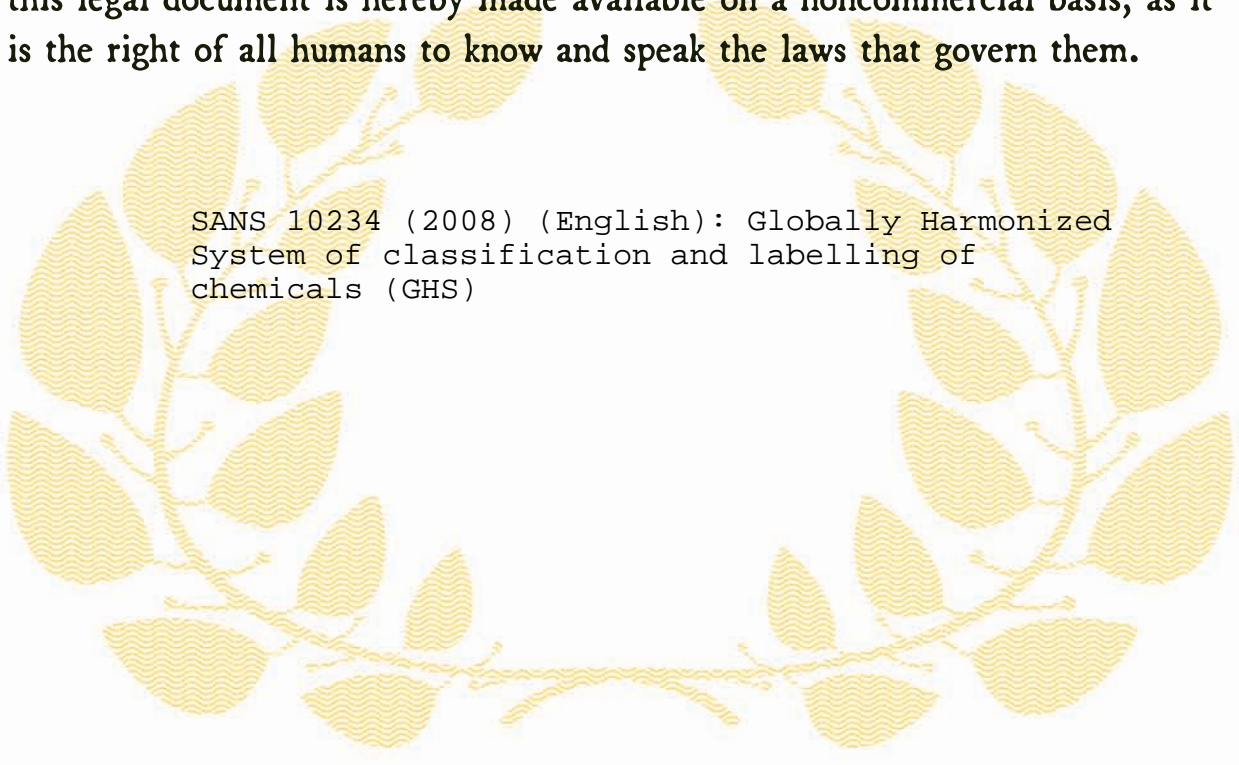




# *Republic of South Africa*

## EDICT OF GOVERNMENT

In order to promote public education and public safety, equal justice for all, a better informed citizenry, the rule of law, world trade and world peace, this legal document is hereby made available on a noncommercial basis, as it is the right of all humans to know and speak the laws that govern them.



SANS 10234 (2008) (English): Globally Harmonized  
System of classification and labelling of  
chemicals (GHS)



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**SANS 10234:2008**

Edition 1.1

## **SOUTH AFRICAN NATIONAL STANDARD**

### **Globally Harmonized System of classification and labelling of chemicals (GHS)**

**Warning — Can only be used in conjunction  
with the [Supplement to SANS 10234](#)**

## SANS 10234:2008

Edition 1.1

### Table of changes

Change No.	Date	Scope
Amdt 1	2008	Amended to include a reference to the Supplement to SANS 10234; exemption of stock remedies from the requirements; addition of "crustacea" to the definitions of environmental toxicity; removal of the colour orange from the pesticide colour band requirements; amendment of the classification criteria for category 2 skin irritants and category 3 acute dermal toxicity; correction of the text of health hazard statements and the numbering of environmental hazard statements; correction of the concentration limits for salinity of the marine test medium.

## Acknowledgement

Standards South Africa wishes to acknowledge the valuable assistance derived from publications by the United Nations Transport Division, Geneva, Switzerland.

## Foreword

This South African standard was approved by National Committee SABS SC 1060B, *National committee for dangerous goods standards – Classification and information*, in accordance with procedures of the SABS Standards Division in compliance with annex 3 of the WTO/TBT agreement.

This document was published in December 2008. This document supersedes SANS 10234:2007 (edition 1).

Owing to the fact that information in respect of names and addresses of competent authorities and certification authorities dealing with dangerous goods is subject to change, details of the competent authorities and certification authorities are given in a general advice sheet provided with this standard. This advice sheet will be updated every six months and it is the responsibility of the competent authority/certification authority to notify Standards South Africa of any changes. The advice sheet will be available, free of charge, from the Standards Sales Department of Standards South Africa.

The Supplement to SANS 10234 *List of GHS classification and labelling of chemicals* consists of an alphabetical list of chemicals classified in accordance with the GHS and a numerical list of the re-classified chemicals in accordance with the CAS (Chemical Abstracts Registry) numbers. **Amdt 1**

Annexes A, B and J form an integral part of this standard.

Annexes C, D, E, F, G, H, and I are for information only.

In **5.2.2** mention is made of "accredited laboratories". In South Africa this refers to laboratories that are accredited by SANAS (South African Accreditation System).

In **6.5.1** mention is made of "national qualifications authority". In South Africa this is the South African Qualifications Authority (SAQA).

In **6.7.2.9.2.1** it is required that colour bands be used on pesticide labels. In South Africa labelling of pesticides is regulated by the Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) (as amended).

## **Foreword** *(concluded)*

In **6.7.5.12** mention is made of the registration number required before a pesticide can be placed on the market. In South Africa this is regulated by The Registrar, Act 36/1947 in accordance with the Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) (as amended)

In **8.1.2** mention is made of national legislation, provisions and requirements for SDSs. In South Africa, SDSs are regulated by the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

In **C.4.9.1.1** reference is made to “occupational exposure limit(s)”. In South Africa, the permissible concentration of hazardous air-borne substances is regulated by the Hazardous Chemical Substances Regulations of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

## **Introduction**

The use of chemical products to enhance and improve life is a widespread practice worldwide. But alongside the benefits of these products, there is also potential for adverse effects to people or the environment.

Given the reality of the extensive global trade in chemicals, it was recognized that a globally harmonized approach to the classification, labelling and Safety Data Sheets (SDS) for chemicals is imperative.

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## **Globally Harmonized System of classification and labelling of chemicals (GHS)**

### **1 Scope**

This standard covers the harmonized criteria for the classification of hazardous substances and mixtures, including waste, for their safe transport, use at the workplace or in the home according to their health, environmental and physical hazards, for example acute toxicity and flammability. It gives the harmonized communication elements for labelling and safety data sheets.

The classification and labelling of pharmaceuticals (including stock remedies), food additives, cosmetics, and pesticide residues in food are not covered by this standard in terms of labelling at the point of intentional intake. However, they are covered by the standard where workers might be exposed to them and in transport if the potential exposure warrants.

**Amdt 1**

### **2 Normative references**

The following referenced documents are indispensable for the application of this document. All normative documents are subject to revision and, since any reference to a normative document is deemed to be a reference to the latest edition of that document, parties to agreements based on this document are encouraged to take steps to ensure the use of the most recent editions of the normative documents indicated below. Information on currently valid national and international standards can be obtained from the SABS Standards Division.

#### **2.1 Standards**

ASTM D445, *Standard test method for kinematic viscosity of transparent and opaque liquids (and calculations of the dynamic viscosity)*.

ASTM D4359-90, *Standard test method for determining whether a material is a liquid or a solid*.

ISO 2137, *Petroleum products – Lubricating grease and petrolatum – Determination of cone penetration*.

ISO 3219, *Plastics, polymers/resins in the liquid state or as emulsions or dispersions – Determination of viscosity using a rotational viscometer with defined shear rate*.

ISO 6503, *Paints and varnishes – Determination of total lead – Flame atomic absorption spectrometric method*.

ISO 8317, *Child-resistant packaging – Requirements and testing procedures for reclosable packages*.

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ISO 10156, *Gases and gas mixtures – Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets.*

ISO 10156-2, *Gas cylinders – Gases and gas mixtures – Part 2: Determination of oxidizing ability of toxic and corrosive gases and gas mixtures.*

ISO 11683, *Packaging – Tactile warnings of danger – Requirements.*

[SANS 10228, \*The identification and classification of dangerous goods for transport.\*](#)

[SANS 10229-1, \*Transport of dangerous goods – Packaging and large packaging of dangerous goods for road and rail transport – Part 1: Packaging.\*](#)

[SANS 10233 \(SABS 0233\), \*Transport of dangerous goods – Intermediate bulk containers.\*](#)

## **2.2 Other publications**

United Nations' *Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria.*

NOTE The United Nations' *Recommendations on the transport of dangerous goods, Manual of tests and criteria*, will be referred to as the United Nations' *Manual of tests and criteria* in the text of this standard.

*Recommendations on the Transport of Dangerous Goods, Model Regulations* the latest revised edition of the United Nations publication bearing this title, and any published amendment thereto.

## **3 Definitions and abbreviations**

### **3.1 Definitions**

For the purposes of this document, the following definitions apply.

#### **3.1.1**

##### **abiotic**

incompatible with life

#### **3.1.2**

##### **aerosol**

non-refillable receptacle made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state

NOTE Aerosol includes aerosol dispensers.

#### **3.1.3**

##### **acute aquatic toxicity**

intrinsic property of a substance to be injurious to an aquatic organism following short-term exposure to that substance

#### **3.1.4**

##### **acute toxicity**

adverse effects occurring after oral or dermal administration of a single dose of a substance, or multiple doses given within 24 h, or an inhalation exposure of 4 h

**3.1.5**

**alloy**

metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means

NOTE An alloy is considered to be a mixture for purposes of classification in accordance with this standard.

**3.1.6**

**aspiration**

entry of a liquid or a solid chemical product into the trachea and lower respiratory system directly through the oral or nasal cavity, or indirectly from vomiting

**3.1.7**

**availability**

extent to which a substance becomes a soluble or disaggregate species (see also 3.1.55 for metal availability)

**3.1.8**

**bioaccumulation**

net result of uptake, transformation and elimination of a substance in an organism due to all routes of exposure (air, water, sediment/soil and food)

**3.1.9**

**bioavailability**

extent to which a substance is taken up by an organism and distributed to an area within the organism

NOTE 1 Bioavailability is dependent upon the physico-chemical properties of a substance, the anatomy and the physiology of the organism, pharmacokinetics, and the route of exposure.

NOTE 2 Availability (see 3.1.7 and 3.1.55) is not a prerequisite for bioavailability.

**3.1.10**

**bioconcentration**

net result of uptake, transformation and elimination of a substance in an organism due to waterborne exposure

**3.1.11**

**bio concentration factor (BCF)**

ratio of the concentration of a test substance in a test organism to the concentration of the test substance in the test water at equilibrium

**3.1.12**

**biotic**

relating to life or to living things

**3.1.13**

**carcinogen**

chemical substance or a mixture of chemical substances which induce cancer or increase its incidence when inhaled, ingested or absorbed through the skin

**3.1.14**

**CAS number**

number allocated to a chemical by the American Chemical Society's Abstract Service

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### **3.1.15**

#### **chemical identity**

name that uniquely identifies a chemical

NOTE This can be a name that is in accordance with the nomenclature systems of the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS), or a technical name.

### **3.1.16**

#### **chronic aquatic toxicity**

potential or actual properties of a substance to cause adverse effects to aquatic organisms during exposures that are determined in relation to the life-cycle of the organism

### **3.1.17**

#### **competent authority**

national body or authority designated or otherwise recognized as such in connection with the Globally Harmonized System of classification and labelling of chemicals (GHS)

### **3.1.18**

#### **compressed gas**

gas which, when packaged under pressure, is entirely gaseous at  $-50\text{ }^{\circ}\text{C}$ ; including all gases with a critical temperature of  $-50\text{ }^{\circ}\text{C}$  or less

### **3.1.19**

#### **contact sensitizer**

substance that will induce an allergic response following skin contact

NOTE "Contact sensitizer" is equivalent to "skin sensitizer" (see 3.1.79).

### **3.1.20**

#### **control temperature**

maximum temperature at which an organic peroxide can be safely transported, handled or stored

### **3.1.21**

#### **corrosive to metal**

substance or a mixture which, by chemical action, will materially damage, or even destroy, metals

### **3.1.22**

#### **critical temperature**

temperature above which a pure gas cannot be liquefied, regardless of the degree of compression

### **3.1.23**

#### **degradation**

decomposition of organic molecules to smaller molecules and eventually to carbon dioxide, water and salts

### **3.1.24**

#### **dermal corrosion**

production of irreversible damage to intact skin following the application of a test substance for a period of up to 4 h

NOTE "Dermal corrosion" is equivalent to "skin corrosion" (see 3.1.77).

**3.1.25**

**dermal irritation**

production of reversible damage to intact skin following the application of a test substance for a period of up to 4 h

NOTE "Dermal irritation" is equivalent to "skin irritation" (see 3.1.78).

**3.1.26**

**designated authority**

body to which the competent authority (see 3.1.17) delegates all, or some of its functions in connection with the GHS

**3.1.27**

**diluent**

organic liquid that is compatible with an organic peroxide and a self-reactive substance, and that has a boiling point of not less than 150 °C (see 9.8.2.2(g))

**3.1.28**

**dissolved gas**

gas which, when packaged under pressure, is dissolved in a liquid phase solvent

**3.1.29**

**dust**

solid particles of a substance or a mixture suspended in a gas (usually air)

**3.1.30**

**EC<sub>50</sub>**

concentration of a substance, in milligram per litre of water, that causes the maximum response to 50 % of a population of daphnia (water flea) and crustacea

Amdt 1

**3.1.31**

**EC Number (ECN)**

reference number used by the European Communities to identify dangerous substances, in particular those registered under EINECS

**3.1.32**

**emergency temperature**

temperature at which there is a loss of temperature control (see 3.1.20) and emergency procedures are to be implemented

**3.1.33**

**ErC<sub>50</sub>**

concentration of a substance, in milligram per litre of water, that causes a 50 % reduction of growth rate to a population of daphnia (water flea) and crustacea

Amdt 1

**3.1.34**

**explosive article**

article containing one or more explosive substances

**3.1.35**

**explosive substance**

substance in solid, liquid, paste or gelatinous form (or a mixture of substances) which is in itself capable, by chemical reaction, of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings

NOTE Pyrotechnic substances are included even when they do not evolve gases.

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### **3.1.36**

#### **explosive, unstable**

thermally unstable or too sensitive (or both) for normal handling, transport and use

### **3.1.37**

#### **eye irritation**

production of changes in the eye following the application of a test substance to the anterior surface of the eye, which are fully reversible within 21 d of application

### **3.1.38**

#### **flammable gas**

gas that has a flammable range with air at 20 °C and at a standard pressure of 101,3 kPa

### **3.1.39**

#### **flammable liquid**

liquid that has a closed-cup flash point not exceeding 93 °C

NOTE For transport purposes, hazard category 1 to hazard category 3 apply (see 9.6.1.1 and table 9).

### **3.1.40**

#### **flammable solid**

solid which is readily combustible, or can cause, or contribute to, fire through friction

### **3.1.41**

#### **flash point**

lowest temperature (corrected to a standard pressure of 101,3 kPa) at which the application of an ignition source causes the vapours of a liquid to ignite under specified test conditions

### **3.1.42**

#### **gas**

substance which, at a temperature of 50 °C has a vapour pressure greater than 300 kPa or is completely gaseous at 20 °C at a standard pressure of 101,3 kPa

NOTE Gases are characterized by very low density and viscosity (relative to liquids and solids), comparatively great expansion and contraction with changes in pressure and temperature, the ability to diffuse readily into other gases, and the ability to occupy with almost complete uniformity the whole of any container.

### **3.1.43**

#### **hazard category**

division of criteria within each hazard class, for example oral acute toxicity includes five hazard categories and flammable liquids includes four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally

### **3.1.44**

#### **hazard class**

nature of the physical, health or environmental hazard, for example flammability, carcinogenicity or acute toxicity

### **3.1.45**

#### **hazard statement**

statement assigned to a hazard class and category that describes the nature of the hazards of a hazardous product, including, where appropriate, the degree of hazard



**3.1.46**

**initial boiling point**

temperature of a liquid at which its vapour pressure is equal to the standard pressure (101,3 kPa), that is, the first gas bubble appears

**3.1.47**

**label**

group of written, printed or graphic information elements concerning a hazardous product, selected as relevant to the target sector (s), that is affixed to, printed on, or attached to the immediate container of a hazardous product, or to the outside packaging of a hazardous product

**3.1.48**

**label element**

one type of information that has been harmonized for use in a label, for example, a pictogram (see 3.1.62) or a signal word (see 3.1.76)

**3.1.49**

**$LC_{50}$**

concentration of a substance in air or in water which causes the death of 50 % of a group of test animals

**3.1.50**

**$LD_{50}$**

concentration of a substance, expressed in milligram per kilogram of body mass, which causes the death of 50 % of a group of test animals when ingested, or exposed to the bare skin, all at once

**3.1.51**

**$L(E)C_{50}$**

$LC_{50}$  (see 3.1.49) or  $EC_{50}$  (see 3.1.30)

**3.1.52**

**liquefied gas**

gas which, when packaged under pressure, is partially liquid at temperatures above -50 °C

NOTE A distinction is made between:

- a) a high pressure liquefied gas with a critical temperature between -50 °C and +65 °C; and
- b) a low pressure liquefied gas with a critical temperature above +65 °C

**3.1.53**

**liquid**

substance or a mixture which, at 50 °C, has a vapour pressure of not more than 300 kPa (3 bar), which is not completely gaseous at 20 °C and at a standard pressure of 101,3 kPa, and which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101,3 kPa

NOTE A viscous substance or a viscous mixture for which a specific melting point cannot be determined should be tested in accordance with ASTM D4359-90 or the test for fluidity in accordance with ISO 2137.

**3.1.54**

**mixture**

solid or a solution composed of two or more substances that do not react with each other

**3.1.55**

**metal availability**

extent to which the metal portion of a metal compound can disaggregate from the rest of the compound (molecule) (see also 3.1.7)

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### **3.1.56**

#### **mist**

liquid droplets of a substance or a mixture suspended in a gas (usually air)

### **3.1.57**

#### **mutagen**

agent giving rise to an increased occurrence of mutations in populations of cells or organisms (or both)

### **3.1.58**

#### **mutation**

permanent change in the amount or structure of the genetic material in a cell

### **3.1.59**

#### **octanol-water partition coefficient ( $\log K_{ow}$ )**

measure of the transfer of a substance from the aquatic environment to an organism, for example, fish, and the potential bioaccumulation of the substance at equilibrium concentration

NOTE The partition coefficient is the quotient of octanol to water and is given in the form of its logarithm to base ten.

### **3.1.60**

#### **organic peroxide**

liquid or solid organic substance which contains the bivalent -O-O- structure which can be considered a derivative of hydrogen peroxide where one or both of the hydrogen atoms have been replaced by organic radicals

NOTE The term also includes organic peroxide formulations (mixtures).

### **3.1.61**

#### **oxidizing**

#### **3.1.61.1**

##### **gas**

gas which can, generally by providing oxygen, cause or contribute to the combustion of other material more than air does

#### **3.1.61.2**

##### **liquid**

liquid which, while in itself not necessarily combustible can, generally by yielding oxygen, cause, or contribute to the combustion of other material

#### **3.1.61.3**

##### **solid**

solid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material

### **3.1.62**

#### **pictogram**

graphical composition that can include a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information

**3.1.63**

**precautionary statement**

phrase or pictogram (or both) that describes recommended measures that should be taken into account to minimize or prevent adverse effects resulting from exposure to a hazardous product, or improper storage or handling of a hazardous product

**3.1.64**

**product identifier**

name or number used for a hazardous product on a label or in the SDS. It provides a unique means by which the product user can identify the substance or mixture within the particular use setting, for example transport, consumer or workplace

**3.1.65**

**pyrophoric substance**

liquid or a solid substance which, even in small quantities, is liable of igniting within five minutes after coming into contact with air

**3.1.66**

**pyrotechnic article**

article containing one or more pyrotechnic substances (see 3.1.67)

**3.1.67**

**pyrotechnic substance**

substance or a mixture of substances designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions

**3.1.68**

**readily combustible solid**

powdered, granular, or pasty substance or mixture which is dangerous if it can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly

**3.1.69**

**refrigerated liquefied gas**

gas which, when packaged, is made partially liquid because of its low temperature (see also 3.1.52)

**3.1.70**

**reproductive toxicity**

adverse effects on sexual functions and fertility in adult males and females as well as adverse effects on the development of offspring

**3.1.71**

**respiratory sensitizer**

substance that induces hypersensitivity of the airways following inhalation of the substance

**3.1.72**

**self-accelerating decomposition temperature (SADT)**

lowest temperature at which self-accelerating decomposition occurs with substance as packaged

**3.1.73**

**self-heating substance**

solid or liquid substance, other than a pyrophoric substance, which, by reaction with air and without energy supply, is liable to self-heat; this substance differs from a pyrophoric substance in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days)

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### **3.1.74**

#### **self-reactive substance**

thermally unstable liquid or solid substance liable to undergo a strongly exothermic decomposition even without participation of oxygen (air)

NOTE This definition excludes substances or mixtures classified under the GHS as explosive, organic peroxides or oxidizing.

### **3.1.75**

#### **serious eye damage**

production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 d of application

### **3.1.76**

#### **signal word**

word used to indicate the relative level of severity of hazard and alert the user of a chemical to a potential hazard on the label

NOTE The GHS uses 'Danger' and 'Warning' as signal words.

### **3.1.77**

#### **skin corrosion**

production of irreversible damage to the skin following the application of a test substance for up to 4 h

### **3.1.78**

#### **skin irritation**

production of reversible damage to the skin following the application of a test substance for up to 4 h

### **3.1.79**

#### **skin sensitizer**

substance that will induce an allergic response following skin contact

NOTE "Skin sensitizer" is equivalent to "contact sensitizer" (see 3.1.19).

### **3.1.80**

#### **solid**

powders, flakes granules and kibbles, and also pastes and viscous substances that conform to the test for solids in accordance with ASTM D4359-90

### **3.1.81**

#### **substance**

chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

### **3.1.82**

#### **substance that, on contact with water, emits flammable gases**

solid or liquid substance or mixture which, by interaction with water, is liable to become spontaneously flammable or to give off flammable gases in dangerous quantities

**3.1.83**

**supplemental label element**

additional non-harmonized type of information supplied on the container of a hazardous product that is not required or specified under the GHS

**3.1.84**

**symbol**

graphical element intended to succinctly convey information

**3.1.85**

**technical name**

name that is generally used in commerce, regulations and codes to identify a substance or mixture, other than the IUPAC or CAS name, and that is recognized by the scientific community

NOTE Examples of technical names include those used for complex mixtures (for example, petroleum fractions or natural products), pesticides (for example ISO or ANSI systems), dyestuffs (Colour Index System) and minerals.

**3.1.86**

**vapour**

gaseous form of a substance or a mixture released from its liquid or solid state

**3.1.87**

**viscosity**

**3.1.87.1**

**dynamic**

force per unit area ( $\text{N/m}^2$ ) required to maintain a unit difference of velocity (1 m/s) between two parallel layers one metre apart

**3.1.87.2**

**kinematic**

internal resistance to flow exhibited by a fluid

**3.2 Abbreviations**

**3.2.1 ASTM**

– American Society of Testing and Materials

**3.2.2 BCF**

– bioconcentration factor

**3.2.3 BOD/COD**

– biochemical oxygen demand/chemical oxygen demand

**3.2.4 CA**

– competent authority

**3.2.5 CAS**

– Chemical Abstract Service

**3.2.6 CBI**

– confidential business information

**3.2.7 ECOSOC**

– Economic and Social Council of the United Nations

**3.2.8 EINECS**

– European Inventory of Existing Commercial Chemical Substances

**3.2.9 EU**

– European Union

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<b>3.2.10</b>	GESAMP	– Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection
<b>3.2.11</b>	GHS	– Globally Harmonized System of classification and labelling of chemicals
<b>3.2.12</b>	IAEA	– International Atomic Energy Agency
<b>3.2.13</b>	IARC	– International Agency for the Research on Cancer
<b>3.2.14</b>	ILO	– International Labour Organization
<b>3.2.15</b>	IMO	– International Maritime Organization
<b>3.2.16</b>	ISO	– International Standards Organization
<b>3.2.17</b>	IUPAC	– International Union of Pure and Applied Chemistry
<b>3.2.18</b>	NOEC	– no observed effect concentration
<b>3.2.19</b>	OECD	– Organization for Economic Cooperation and Development
<b>3.2.20</b>	PCB	polychlorinated biphenyl
<b>3.2.21</b>	ppm	– parts per million
<b>3.2.22</b>	PVC	– polyvinyl chloride
<b>3.2.23</b>	rpm	– revolutions per minute
<b>3.2.24</b>	QSAR	– quantitative structure-activity relationships
<b>3.2.25</b>	SAR	– Structure Activity Relationship
<b>3.2.26</b>	SDS	– Safety Data Sheet
<b>3.2.27</b>	SPR	– Structure Property Relationship
<b>3.2.28</b>	UNCED	– United Nations Conference on Environment and Development
<b>3.2.29</b>	UNCETDG/GHS	– United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of classification and labelling of chemicals
<b>3.2.30</b>	UN	– United Nations
<b>3.2.31</b>	UNSCEGHS	– United Nations Sub-Committee of Experts on the Globally Harmonized System of classification and labelling of chemicals
<b>3.2.32</b>	UNSCETDG	– United Nations Sub-Committee of Experts on the Transport of Dangerous Goods

**3.2.33** WHO – World Health Organization

**3.2.34** WMO – World Meteorological Organization

## **4 Applicability of the GHS**

**4.1** The GHS covers all hazardous chemicals. The mode of application of the hazard communication components, for example labels and safety data sheets, may vary by product category or stage in the life cycle. Target audiences for the GHS include consumers, employers and workers using and handling chemicals in the workplace, workers in waste handling facilities, workers in the transport sector and emergency responders.

**4.2** The GHS does not include the establishment of uniform test methods or promotion of further testing to address health outcomes.

## **5 Classification criteria**

### **5.1 General**

**5.1.1** For the purposes of this standard the classification of substances and mixtures incorporates:

- a) identification of the relevant data regarding the hazards;
- b) subsequent review of the data to ascertain the associated hazards; and
- c) a decision on whether the substance or mixture is classifiable as hazardous and the degree of hazard.

**5.1.2** Test data already generated for the classification of a chemical under the existing systems shall be accepted when classifying the chemical under the harmonized system thereby avoiding duplicative testing and the unnecessary use of test animals.

**5.1.3** The classification of a mixture shall be based on test data of the complete mixture, if available. Where test data are not available for the mixture, bridging principles should be considered to see whether they permit classification of the mixture.

**5.1.4** In addition to the requirements given in 5.1.3, the following conditions should be taken into account in the classification of a mixture in terms of health and environmental hazards:

- a) if test data are not available for the mixture itself; and
- b) if the available information is not sufficient to allow application of the bridging principles,

then the agreed upon method(s) (see 10.1.2.4, 10.2.2.3, 10.3.2.3, 10.4.3.3, 10.5.3.3, 10.6.2.2, 10.7.3.3, 10.8.3.4, 10.9.3.4, 10.10.4.3 and 11.3.4 as relevant), described for estimating the hazards shall be applied.

### **5.2 Biological availability**

**5.2.1** The effect of a substance or mixture on biological and environmental systems is influenced, among other factors, by the physicochemical properties of the substance or mixture and the way in which the ingredient substances are biologically available. Some groups of substances present special problems in this respect, for example some polymers and metals.

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**5.2.2** A substance or a mixture need not be classified when it can be shown by conclusive experimental data obtained from OECD Test Guidelines (see annex J) by an accredited laboratory (see foreword) that the substance or mixture is not biologically available. Similarly, bio-availability should be used, where appropriate, in conjunction with the harmonized classification criteria when classifying mixtures.

NOTE The competent authority (see 3.1.17) could approve other test methods, for example, ASTM methods, if adequate justification was provided.

### **5.3 Evidence from humans**

**5.3.1** For classification purposes, reliable epidemiological data and experience on the effects of chemicals on humans, for example occupational data and accident databases, should be taken into account in the evaluation of the human health hazards of a chemical. Testing on humans solely for hazard identification purposes is not acceptable.

**5.3.2** The route of exposure, for example, ingestion and inhalation, and metabolism studies are pertinent in determining the relevance of an effect in humans. When such information raises doubt about relevance in humans, a lower classification might be warranted. When it is clear that the mechanism or mode of action is not relevant to humans, the substance or mixture need not be classified.

### **5.4 Impurities and additives**

Impurities, additives or individual constituents of a substance or a mixture that are classified as hazardous shall be taken into account for classification purposes if they exceed the cut-off value/concentration limit (see 5.5) for a given hazard class.

### **5.5 Cut-off values/concentration limits**

**5.5.1** When classifying an untested mixture based on the hazards of its ingredients, generic cut-off values/concentration limits for the classified ingredients of a mixture can be used for several hazard classes in the GHS. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some mixtures that contain hazardous ingredients at lower concentrations that still pose an identifiable hazard. In other cases the harmonized cut-off value/concentration limit might be considerably lower than could be expected on the basis of an established non-hazardous level for an ingredient.

**5.5.2** Normally, the generic cut-off values/concentration limits adopted in the GHS should be applied in all jurisdictions and for all sectors. However, if information is available that the hazard of an ingredient is below the generic cut-off value/concentration limit, the mixture containing that ingredient should be classified accordingly.

**5.5.3** On occasion, conclusive data may show that the hazard of an ingredient will not be evident when present at a level above the generic GHS cut-off values/concentration limits. In these cases the mixture could be classified according to those data. The data should exclude the possibility that the ingredient would behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture should not contain ingredients that would affect that determination.

**5.5.4** Adequate documentation supporting the use of any values other than the generic cut-off values/concentration limits shall be retained and made available for review on request of the competent authority.



## **5.6 Synergistic or antagonistic effects**

All available information about the potential occurrence of synergistic effects among the ingredients of a mixture shall be taken into account when performing an assessment in accordance with the requirements of this standard. The classification of a mixture to a less hazardous category on the basis of antagonistic effects shall be done **only** if the determination is supported by sufficient data.

## **6 Labelling**

### **6.1 General**

**6.1.1** For the purposes of this standard, a label is the written, printed or graphic material firmly attached to the product container.

**6.1.2** The label is intended to

- a) draw the attention of persons who handle or use the product to its inherent hazard(s),
- b) provide essential information on the hazardous substance(s) present in the product, and
- c) set out the safety measures to be taken into account.

**6.1.3** The hazard symbols (see figure 1), signal words (see 6.7.2.1) and hazard statements (see 6.7.2.2, B.1 and B.2) to be given on a label have all been standardized and assigned to each of the hazard categories. These elements are not subject to variation and shall appear on the label as indicated for each class in the relevant clauses of this standard.

**6.1.4** Packaging of dangerous goods intended for transport is marked with pictograms (hazard labels) that address acute toxicity, physical hazards and environmental hazards (see 6.7.1).

### **6.2 Supplemental label information**

The competent authority (see 3.1.17) or the designated authority (see 3.1.26 and *Advice sheet*), may require supplemental label information to those specified in 6.1.3, or suppliers may choose to add supplementary information on their own initiative. Supplemental label information is permitted, provided that it does not lower the standards of protection and

- a) it does not contradict or cast doubt on the validity of the standardized hazard information, or
- b) it provides information about hazards that are not yet incorporated into the GHS.

### **6.3 Updating of label information**

**6.3.1** The supplier of a hazardous substance or mixture shall update a label as soon as new and significant information about a chemical becomes available. New and significant information is any information that changes the GHS classification of a substance or a mixture and leads to a resulting change in the information provided on the label. This could include new information on the potential adverse chronic health effects of exposure as a result of recently published documentation or test results.

**6.3.2** A supplier shall review the information on which a label is based every 5 years from the date of original preparation, even if no new and significant information has been provided in respect of a substance or a mixture.

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### **6.4 Confidential business information (CBI)**

**6.4.1** If disclosure of the chemical identity of a hazardous substance will put the confidential nature of a chemical at risk, reference to that substance by means of a name that identifies the most important functional groups, for example phenol or amine compound, or by means of an alternative name, is permissible. However, such protection of confidential business information (CBI) shall not compromise the health and safety of workers or consumers, or the protection of the environment.

**6.4.2** In addition to the requirements of 6.4.1, CBI shall be limited to the names of chemicals, and their concentrations in mixtures. All other information shall be disclosed on the label.

**6.4.3** In the event that a competent authority requests confidential information, the reason for the request shall be disclosed to the owner of the CBI and the competent authority shall take the necessary steps to ensure the confidentiality of the information provided.

**6.4.4** The supplier of a hazardous chemical or mixture shall disclose confidential information to a safety or health professional providing medical or other safety and health services to exposed workers or consumers. The person(s) requesting the information shall provide, in writing, specific reasons for the disclosure and shall agree to use the information only for the purpose of consumer or worker protection, and to otherwise maintain its confidentiality.

**6.4.5** Where non-disclosure of CBI is challenged, the competent authority shall address such a challenge. The supplier of a hazardous substance or mixture shall be responsible for supporting the assertion that the withheld information qualifies for CBI protection.

### **6.5 Training**










**6.5.1** Workers and emergency responders shall be trained in the interpretation of labels or SDS information (or both). Training shall be undertaken by service providers registered with the national qualifications authority (see foreword).

**6.5.2** Systems shall be put in place for educating consumers in interpreting label information on the products that they use.

### **6.6 Hazard symbols and pictograms**

#### **6.6.1 Hazard symbols**

The hazard symbols depicted in figure 1 are applicable to the GHS. The symbols shall be in black on a white background.

Flame	Flame over circle	Exploding bomb
		
Corrosion	Gas cylinder	Skull and crossbones
		
Exclamation mark	Environment	Health hazard
		

**Figure 1 — Hazard symbols**

## 6.6.2 Hazard pictograms

**6.6.2.1** The pictograms (commonly referred to as “hazard labels”) prescribed in SANS 10229-1 shall be used for transport purposes. The label for flammable liquids to be depicted on transport packaging is given in figure 2 as an example of a typical hazard label.

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**Figure 2 — GHS pictogram (hazard label) for flammable liquid**

**6.6.2.2** For the purposes of this standard a GHS pictogram shall be in the shape of a square set at a point with a red frame sufficiently wide to be clearly visible. The hazard pictogram for a skin irritant is provided in figure 3 as an example of a typical GHS pictogram.



**Figure 3 — GHS pictogram for skin irritant**

## **6.7 Label elements**

### **6.7.1 Transport label elements**

**6.7.1.1** The requirements for labelling and marking of dangerous goods packaging for transport are covered in SANS 10229-1 and SANS 10233 as relevant.

**6.7.1.2** Where a transport pictogram appears on a label, a GHS pictogram for the same hazard shall not appear.

**6.7.1.3** The GHS pictograms, for example irritant and chronic health effects, are not required for the transport of dangerous goods and shall not be displayed on freight containers, road vehicles, railway wagons or railway tanks.

### **6.7.2 GHS label elements**

#### **6.7.2.1 Signal words**

The signal words (see 3.1.76) "Danger" or "Warning" as applicable, shall be given on a label to indicate the level of severity of a hazard and alert the user of a chemical of a potential hazard. The tables in the individual clauses of this standard for each hazard class detail the signal words that have been assigned to each of the hazard categories.

### **6.7.2.2 Hazard statements**

A hazard statement(s) (see 3.1.45) shall be given on a label to describe the nature of the hazard(s) of a hazardous product including, where appropriate, the degree of hazard. The tables of label elements in the individual clauses of this standard for each hazard class detail the hazard statements that have been assigned to each of the hazard categories.

### **6.7.2.3 Precautionary statements and pictograms**

A precautionary statement (see 3.1.63) or pictogram (3.1.62) (or both) shall be given on a label that describes recommended measures that should be taken to minimise, or prevent, adverse effects resulting from exposure to a hazardous product by handling or improper storage. See annex B for the precautionary statements and pictograms that can be used on a label.

### **6.7.2.4 Product identifier**

**6.7.2.4.1** A product identifier (see 3.1.64) shall be given on a label and it shall match the product identifier used on the SDS. SANS 10228 provides a list of dangerous substances or mixtures that require specific handling during transport. If a substance or a mixture is listed in SANS 10228, the the UN proper shipping name shall also be provided on the package. However, a UN proper shipping name is **not** required on a package if the substance is non-dangerous for transport.

**6.7.2.4.2** The label of a substance shall include the chemical identity of the substance (see 3.1.81). The label of a mixture or an alloy shall include the chemical identities of all ingredients or alloying elements that contribute to acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, skin or respiratory sensitisation, or target organ toxicity, as relevant. See 6.4 for the requirements regarding the disclosure of confidential business information (CBI).

### **6.7.2.5 Supplier identification**

The name, physical address and telephone number of the manufacturer or supplier of the substance or mixture shall be provided on the label.

**Amdt 1**

### **6.7.2.6 Precedence for the allocation of symbols**

For a substance or a mixture covered by SANS 10228, the precedence of symbols for physical hazards shall follow the rules of SANS 10228. In workplace situations, the competent authority could require all symbols for physical hazards to be used. For health hazards, the following principles of precedence apply:

- a) the skull and crossbones takes precedence over the exclamation mark where it is used to indicate that a chemical is harmful;
- b) the corrosive symbol takes precedence over the exclamation mark where it is used to indicate skin or eye irritation; and
- c) the target organ systemic toxicity (health hazard) symbol indicating respiratory sensitization takes precedence over the exclamation mark where it is used for skin sensitization or for skin or eye irritation.

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### 6.7.2.7 Precedence for the allocation of signal words

If the signal word “Danger” applies, the signal word “Warning” shall not appear on the label.

### 6.7.2.8 Precedence for the allocation of hazard statements

No precedence for the allocation of hazards statements is applicable. However, all assigned hazard statements shall appear on the label.

### 6.7.2.9 Layout of labels

#### 6.7.2.9.1 General

**6.7.2.9.1.1** The GHS hazard pictograms, signal word and hazard statements shall be located together on the label.

**6.7.2.9.1.2** The layout of the label elements is at the discretion of the supplier. Examples of how label elements could appear on different packaging are provided in annex E.

**6.7.2.9.1.3** The entire surface of the label shall be firmly affixed to one or more surfaces of the packaging so that the information given on the label can be read horizontally when the package is put in the normal position.

**6.7.2.9.1.4** The dimensions of the labels shall be in accordance with table 1.

**Table 1 — Dimensions of labels**

1	2
Capacity of the package	Dimensions of the label
L	mm
≤ 3	≥ 52 × 74 <sup>a</sup>
> 3 ≤ 50	≥ 74 × 105
> 50 ≤ 500	≥ 105 × 148
> 500	≥ 148 × 210
<sup>a</sup> See 6.7.2.9.1.6	

**6.7.2.9.1.5** The colour and presentation of the label, or of the package itself, shall be such that the hazard symbol(s) and its background stand out clearly. Furthermore, the information given on the label shall stand out clearly from its background and the size and spacing of the lettering shall be such that the lettering is easily legible (see also annex E).

**6.7.2.9.1.6** For very small packages, it is permissible to reduce the size of the label, provided that the lettering is easily legible. The package shall be accompanied by the relevant precautionary statements in the form of an insert or a SDS if it is physical impossible to include the advice on the label of the package.

#### 6.7.2.9.2 Pesticides

**6.7.2.9.2.1** In addition to the requirements of 6.7.2.9.1.5, colour bands shall be used on the labels of pesticides as background for pictograms depicting hazard statements and precautionary statements (see B.32 and the foreword). The colour bands shall visually match colour reference numbers Pantone 192 or NCS S 0580-Y90R (red), Pantone 361 or NCS S 1565-G

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(green), Pantone 300 or NCS S 2065-B (blue) and Pantone 109 or NCS S 0570-G90Y (yellow). In case of a dispute the NCS colours shall take precedence. **Amdt 1**

NOTE 1 The NCS colour chart is available from Colour Centre SA, Postnet Suite 50, Private Bag X9, Melville 2109, fax (011) 482-5419 and e-mail [ncscolour@iafrica.com](mailto:ncscolour@iafrica.com)

NOTE 2 See 6.7.5.12 for other additional provisions pertaining to the labelling of pesticides.

**6.7.2.9.2.2** The colour bands shall be allocated as follows:

- a) **red** – when the signal word “Danger” is assigned;
- b) **yellow** – when the signal word “Warning”, hazard pictogram(s), hazard statements and precautionary statements are assigned;
- c) **blue** – when the signal word “Warning”, hazard statements and precautionary statements are assigned but a hazard pictogram is not required; and
- c) **green** – when no signal word, hazard pictogram(s), hazard statements and precautionary statements are applicable.

### **6.7.3 Workplace labelling**

**6.7.3.1** Products falling within the scope of this standard shall carry the GHS label at the point where they are supplied to the workplace, and that label shall be maintained on the supplied container in the workplace.

**6.7.3.2** The GHS label or label elements shall be used for workplace containers. However, an alternative means of giving workers the same information in a different written or displayed format can be used when such a format is more appropriate to the workplace and communicates the information as effectively as the GHS label.

**6.7.3.3** Alternative means of providing workers with the information contained in a GHS label can be implemented where hazardous chemicals are transferred from an original supplier container into a workplace container or system, or where chemicals are produced in a workplace but are not packaged in containers intended for sale or supply. Chemicals that are produced in a workplace can be contained or stored in many different ways such as:

- a) small samples collected for testing or analysis;
- b) piping systems including valves;
- c) process or reaction vessels;
- d) ore cars;
- e) conveyer systems; or
- f) free-standing bulk storage of solids.

**6.7.3.4** Workers shall be trained to understand the specific communication methods used in a workplace. Training methods shall include

- a) product identifiers together with GHS symbols and other pictograms to describe precautionary measures,

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- b) process flow charts for complex systems to identify chemicals contained in pipes and vessels with links to the appropriate SDS,
- c) displays with GHS symbols,
- d) colour and signal words in piping systems and processing equipment,
- e) permanent placarding for fixed piping,
- f) batch tickets or recipes for labelling batch mixing vessels, and
- g) piping bands with hazard symbols and product identifiers.

### **6.7.4 Consumer product labelling**

The label of a consumer product shall be sufficiently detailed and relevant to the use of the product, as the label is likely to be the sole source of information readily available to the consumer. The label shall provide sufficient information on the likelihood of injury (risk communication) (see annex D) and the likelihood of acute physical, health and environmental hazards (see B.1 and B.2).

### **6.7.5 Special provisions for the labelling of certain products**

#### **6.7.5.1 Labels for paints and varnishes that contain lead**

The package label of paint and varnish that has a lead content exceeding 0,15 % Pb (by mass), as determined in accordance with ISO 6503, shall bear the following warning:

- a) **if container content is equal to or exceeds 125 mL:** "Warning! Contains lead. Should not be used on surfaces liable to be chewed or sucked by children."
- b) **if container content is less than 125 mL:** "Warning! Contains lead."

#### **6.7.5.2 Labels for adhesives that contain cyanoacrylates**

**6.7.5.2.1** The package label of an adhesive that is based on cyanoacrylates shall bear the following warning:

Cyanoacrylate.

Danger.

Bonds to skin and eyes in seconds.

Keep out of reach of children.

**6.7.5.2.2** Appropriate safety advice on cyanoacrylates shall accompany the package.

#### **6.7.5.3 Labels for products that contain isocyanates**

The package label of a product that contains isocyanates, for example as monomers, oligomers, prepolymers, or as mixtures thereof, shall bear the following inscription:

Contains isocyanates.

See information supplied by the manufacturer.



#### **6.7.5.4 Labels for products that contain epoxy constituents**

The package label of a product that contains epoxy constituents with an average molecular mass equal to or below 700, shall bear the following inscription:

Contains epoxy.

See information supplied by the manufacturer.

#### **6.7.5.5 Labels for products intended for use by spraying**

The package label of a product intended for use by spraying shall bear the relevant of the following precautionary statements (see B.2.5):

- a) **P260 and P285**, if the spray contains very toxic or toxic substances that are used in industry or in agriculture; or
- b) **P260 and P271**, if the spray contains substances likely to give rise to inhalation, fire or explosion risks and where P285 is inappropriate.

#### **6.7.5.6 Labels for products that have cumulative effects**

The package label of a product that contains at least one substance that has a cumulative effect shall bear the statement "Danger of cumulative effects" if the substance(s) is present at a concentration equal to or exceeding 1 %, and if a different concentration for the substance(s) is not given in the relevant table for concentration limits.

#### **6.7.5.7 Labels for products that contain active chlorine**

The package label of a product that has an active chlorine content exceeding 1 % shall bear the following warning:

Danger!

Do not use together with other products.

May release dangerous gases (chlorine).

#### **6.7.5.8 Labels for products that contain cadmium alloys**

The package label of a product that contains cadmium alloys intended for use in brazing or soldering shall bear the following warning:

Warning!

Contains cadmium.

Dangerous fumes are formed during use.

See information supplied by the manufacturer.

Comply with the safety instructions.

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### **6.7.5.9 Labels for equipment that contains PCBs**

**6.7.5.9.1** In addition to the labelling required in terms of this standard, equipment that contains PCBs shall also display instructions on

- a) the disposal of PCBs, and
- b) the maintenance and use of equipment that contains PCBs.

**6.7.5.9.2** The instructions mentioned in 6.7.5.9.1 shall be so located on the packaging as to be visible when the object containing the PCBs is installed in the normal way. The surface area immediately surrounding the instructions shall be of a colour that contrasts with the background colour of the label.

### **6.7.5.10 Labels for aerosol dispensers**

The label of an aerosol dispenser shall contain the following information in indelible, easily legible lettering:

- a) the name and address or trademark of the company responsible for marketing the product;
- b) the net contents, by volume;
- c) directions for use;
- d) the danger symbol(s); and
- e) the declaration "CFC FREE" plus logo, if applicable.

### **6.7.5.11 Labels for illuminating paraffin (kerosene)**

The package label of an illuminating paraffin (kerosene) container (see 7.2.4(f)), shall contain the following information in indelible, easily legible lettering:

#### **HAZARDS**

Flammable. Very toxic if swallowed. May cause lung damage if swallowed.

#### **PRECAUTIONS**

Keep out of reach of children. Keep only in original container. Keep container tightly closed and at a temperature not exceeding 40 °C. Keep away from food, drink and animal feed. Do not breathe the fumes. Use only in well ventilated areas. Avoid contact with skin and eyes. Turn off all appliances and put out all flames before going to sleep or when you leave your home.

#### **FIRST AID**

If swallowed, do not give the person anything to drink. Do not make them vomit. Seek medical advice immediately and show the container or label.

In case of contact with eyes, immediately rinse with plenty of water and seek medical advice. After contact with skin, immediately wash with plenty of soap and water.

In case of burn, immediately immerse the affected area in cool water for 20 min and get the person to a hospital or clinic quickly.

## FIRE FIGHTING

If a fire extinguisher is not available, put out the fire with dry sand, NOT water. Throw the sand at the base of the fire. In case of an uncontrolled fire, get out fast and call the Fire Brigade.

### **6.7.5.12 Labels for pesticides**

In addition to the requirements of 6.7.2.9.2, the package label of a pesticide shall contain the following information in indelible, easily legible lettering:

- a) the registration number required before a pesticide can be placed on the market (see foreword);
- b) the name and address of the registration holder; and
- c) a note to the physician on the medical treatment in case of an accident.

NOTE See example 8 of annex E for an example of a pesticide label.

## **7 Packaging**

### **7.1 General**

**7.1.1** Packaging is used for the containment, protection, handling, delivery and presentation of goods from the producer to the user or consumer.

**7.1.2** For the purposes of this standard, packaging constitutes the following:

- a) a sales unit to the consumer at the point of purchase;
- b) a certain number of sales units in a packaging to be sold as such to the final user or consumer. The packages can also be used to replenish the shelves at a retailer, provided that a sales unit can be removed from the packaging without affecting the characteristics of the product; and
- c) transport packaging to facilitate handling and transport of a number of sales units or grouped packaging in order to prevent damage due to physical handling and transport (see SANS 10229-1).

**7.1.3** Packaging shall be of good fabrication and shall be so designed, constructed and closed as to prevent deformation, leakage or sifting of the contents due to vibration, stacking, impact or changes in environmental conditions, such as temperature, pressure or humidity, that can be encountered during handling. Packaging intended for transport shall be tested and certified in accordance with SANS 10229-1.

**7.1.4** The material that constitutes the packaging and closing devices shall not be susceptible to adverse attack by the contents, or be liable to form dangerous compounds with the contents.

**7.1.5** Packaging and closing devices shall be strong and solid to ensure that they will not be worked loose during handling and that they will withstand the normal stresses and strains of handling.

**7.1.6** A package fitted with a replaceable closure shall be so designed that the packaging can be opened and closed repeatedly without loss or leakage of the contents.

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### **7.2 Child-resistant closures (CRCs) and tactile warnings**

**7.2.1** A package that contains a hazardous substance or a hazardous mixture of acute toxicity category 1 and category 2, or a corrosive substance of category 1, to be sold, or made available to the general public, shall be fitted with a CRC in accordance with ISO 8317 and shall bear a tactile warning conforming to ISO 11683 (see also 7.2.3 and 7.2.4).

**7.2.2** A package that contains a hazardous substance or mixture to be sold, or made available to the general public and that is labelled "toxic", "extremely flammable" or "highly flammable", shall bear a tactile warning of danger.

**7.2.3** A package that contains a hazardous substance or mixture that has one of the characteristics given in (a) or (b) below and that is to be sold, or made available to the general public, shall be fitted with a CRC:

a) liquids

- 1) that have a kinematic viscosity of less than 7,0 mm<sup>2</sup>/s at 40 °C, as determined in accordance with ISO 3219 and ASTM D445 (identical to IP 71), and
- 2) that have an aliphatic or aromatic hydrocarbon content (or both) equal to or greater than 10 %, by mass, for example, thinners and petrol; and

b) mixtures that contain at least one of the following substances:

methanol, at a concentration equal to or exceeding 3 %, for example, methylated spirits; or chloromethane, at a concentration equal to or exceeding 1 %.

**7.2.4** In addition to the dangerous substances and mixtures required in terms of 7.2.1 and 7.2.3 to have a CRC, the following products shall also be fitted with CRCs:

- a) those that are manufactured for direct sale, marketing and distribution for household use, and for bulk sale to be decanted for household use into containers of 20 L or less;
- b) curatives for unsaturated polyester resins (as used in the production of glass-reinforced composites), epoxy resins, polyurethanes and other thermoset materials;
- c) automatic dishwasher detergents, automatic washing detergents and toilet cleaners;
- d) brake (hydraulic fluid) and anti-freezing agents;
- e) swimming pool chemicals based on calcium hypochlorite or trichloroisocyanuric acid and its salts; and
- f) illuminating paraffin (kerosene). Additionally, the illuminating paraffin shall be packed in dedicated containers and any other plastics containers which shall be impervious to the product.

## **8 Safety data sheets**

### **8.1 General**

**8.1.1** A safety data sheet (SDS) shall be produced for all substances and mixtures which meet the harmonized criteria for physical, health or environmental hazards under the GHS and for all mixtures which contain substances that meet the criteria for carcinogenic, toxic to reproduction or target organ toxicity in concentrations exceeding the cut-off values/concentration limits specified by

the criteria for mixtures (see table 2). The competent authority can also require SDSs for mixtures not meeting the criteria for classification as hazardous but which contain hazardous substances in certain concentrations.

**Table 2 — Cut-off values/concentration limits for hazard classes**

1	2
Hazard class	Cut-off value (concentration limit)  %
Acute toxicity	$\geq 1,0$
Skin corrosion	$\geq 1,0$
Skin irritation	$\geq 1,0$
Serious damage to eyes	$\geq 1,0$
Eye irritation	$\geq 1,0$
Respiratory sensitisation	$\geq 1,0$
Skin sensitisation	$\geq 1,0$
Mutagenicity:	
Category 1	$\geq 0,1$
Category 2	$\geq 1,0$
Carcinogenicity	$\geq 0,1$
Reproductive toxicity	$\geq 0,1$
Target organ systemic toxicity	
Single exposure	$\geq 1,0$
Repeat exposure	$\geq 1,0$
Hazardous to the aquatic environment	$\geq 1,0$

**8.1.2** Every supplier, manufacturer, importer or distributor of a hazardous substance or mixture intended for use at a workplace shall provide the party receiving such a substance or mixture with an SDS, free of charge. The SDS shall contain the information as set out in 8.2 and table 3 (see also annex C) and as stipulated in the relevant national legislation, provisions, and requirements (see foreword).

**8.1.3** Any new information on the substance or mixture that becomes known to the supplier, manufacturer, importer or distributor shall be forwarded to the recipient of the SDS, free of charge.

**8.1.4** An SDS need not be supplied when a substance or mixture offered or sold in the retail trade is furnished with sufficient information to enable users to take the necessary measures with regard to the protection of health and safety. However, an SDS shall be supplied at the request of any interested or affected person, free of charge.

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### **8.2 SDS format**

The information in the SDS shall be presented using the following sixteen headings in the order given below.

1. Identification
2. Hazard(s) identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

### **8.3 SDS content**

**8.3.1** An SDS shall provide a clear description of the data used to identify the hazards. The minimum information given in table 3 shall be included, where applicable and available, on the SDS under the relevant headings. If specific information is not applicable or not available under a particular subheading, it shall be clearly stated.

**8.3.2** Some subheadings relate to information that is national or regional in nature, for example "EC number" and "occupational exposure limits". Information should be included under such SDS subheadings that are appropriate and relevant to the countries or regions for which the SDS is intended and into which the product is being supplied.

**8.3.3** Guidance on the preparation of an SDS under the requirements of the GHS can be found in annex C.

**Table 3 — Minimum information for an SDS**

1	2	3
Section	Description	Requirements
<b>1</b>	<b>Identification of the substance or mixture and of the supplier</b>	<ul style="list-style-type: none"> <li>• GHS product identifier.</li> <li>• Other means of identification.</li> <li>• Recommended use of the chemical and restrictions on use.</li> <li>• Supplier's details (including name, address, phone number etc).</li> <li>• Emergency phone number.</li> </ul>
<b>2</b>	<b>Hazards identification</b>	<ul style="list-style-type: none"> <li>• GHS classification of the substance/mixture and any national or regional information.</li> <li>• GHS label elements, including precautionary statements. (hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol e.g. flame, skull and crossbones.)</li> <li>• Other hazards which do not result in classification (e.g. dust explosion hazard) or are not covered by the GHS.</li> </ul>
<b>3</b>	<b>Composition/information on ingredients</b>	<p><b><u>Substance</u></b></p> <ul style="list-style-type: none"> <li>• Chemical identity.</li> <li>• Common name, synonyms, etc.</li> <li>• CAS number, and other unique identifiers.</li> <li>• Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.</li> </ul> <p><b><u>Mixture</u></b></p> <ul style="list-style-type: none"> <li>• The chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels.</li> </ul>
<b>4</b>	<b>First aid measures</b>	<ul style="list-style-type: none"> <li>• Description of necessary measures, subdivided according to the different routes of exposure, i.e. inhalation, skin and eye contact and ingestion.</li> <li>• Most important symptoms/effects, acute and delayed.</li> <li>• Indication of immediate medical attention and special treatment needed, if necessary.</li> </ul>
<b>5</b>	<b>Fire-fighting measures</b>	<ul style="list-style-type: none"> <li>• Suitable (and unsuitable) extinguishing media.</li> <li>• Specific hazards arising from the chemical (e.g. nature of any hazardous combustion products).</li> <li>• Special protective equipment and precautions for fire-fighters.</li> </ul>
<b>6</b>	<b>Accidental release measures</b>	<ul style="list-style-type: none"> <li>• Personal precautions, protective equipment and emergency procedures.</li> <li>• Environmental precautions.</li> <li>• Methods and materials for containment and cleaning up.</li> </ul>
<b>7</b>	<b>Handling and storage</b>	<ul style="list-style-type: none"> <li>• Precautions for safe handling.</li> <li>• Conditions for safe storage, including any incompatibilities.</li> </ul>

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**Table 3** (*continued*)

1	2	3
Section	Description	Requirements
<b>8</b>	<b>Exposure controls/personal protection</b>	<ul style="list-style-type: none"> <li>• Control parameters e.g. occupational exposure limit values or biological limit values.</li> <li>• Appropriate engineering controls.</li> <li>• Individual protection measures, such as personal protective equipment.</li> </ul>
<b>9</b>	<b>Physical and chemical properties</b>	<ul style="list-style-type: none"> <li>• Appearance (physical state, colour etc).</li> <li>• Odour.</li> <li>• Odour threshold.</li> <li>• pH.</li> <li>• Melting point/freezing point.</li> <li>• Initial boiling point and boiling range.</li> <li>• Flash point.</li> <li>• Evaporation rate.</li> <li>• Flammability (solid, gas).</li> <li>• Upper/lower flammability or explosive limits.</li> <li>• Vapour pressure.</li> <li>• Vapour density.</li> <li>• Relative density.</li> <li>• Solubility(ies).</li> <li>• Partition coefficient: n-octanol/water</li> <li>• Auto-ignition temperature.</li> <li>• Decomposition temperature.</li> </ul>
<b>10</b>	<b>Stability and reactivity</b>	<ul style="list-style-type: none"> <li>• Chemical stability.</li> <li>• Possibility of hazardous reactions.</li> <li>• Conditions to avoid (e.g. static discharge, shock or vibration).</li> <li>• Incompatible materials.</li> <li>• Hazardous decomposition products.</li> </ul>
<b>11</b>	<b>Toxicological information</b>	<ul style="list-style-type: none"> <li>• Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects, including:</li> <li>• information on the likely routes of exposure (inhalation, ingestion, skin and eye contact);</li> <li>• Symptoms related to the physical, chemical and toxicological characteristics;</li> <li>• Delayed and immediate effects and also chronic effects from short- and long-term exposure;</li> <li>• Numerical measures of toxicity (such as acute toxicity estimates).</li> </ul>
<b>12</b>	<b>Ecological information</b>	<ul style="list-style-type: none"> <li>• Ecotoxicity (aquatic and terrestrial, where available).</li> <li>• Persistence and degradability.</li> <li>• Bioaccumulative potential.</li> <li>• Mobility in soil.</li> <li>• Other adverse effects.</li> </ul>
<b>13</b>	<b>Disposal considerations</b>	<ul style="list-style-type: none"> <li>• Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.</li> </ul>



**Table 3** (*concluded*)

1	2	3
Section	Description	Requirements
<b>14</b>	<b>Transport information</b>	<ul style="list-style-type: none"> <li>• UN number.</li> <li>• UN Proper shipping name.</li> <li>• Transport hazard class(es).</li> <li>• Packing group, if applicable.</li> <li>• Marine pollutant (Yes/No).</li> <li>• Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises.</li> </ul>
<b>15</b>	<b>Regulatory information</b>	<ul style="list-style-type: none"> <li>• Safety, health and environmental regulations specific for the product in question.</li> </ul>
<b>16</b>	<b>Other information including information on preparation and revision of the SDS</b>	

## 9 Physical hazards

### 9.1 Explosives

#### 9.1.1 General

**9.1.1.1** An explosive substance (see 3.1.35) is a solid substance or a liquid substance, or a mixture of substances, which is in itself capable, by chemical reaction, of producing gas at such a temperature, pressure and speed as to cause damage to the surroundings. Pyrotechnic substances are included even when they do not evolve gases.

**9.1.1.2** An explosive article is an article containing one or more explosive substances or mixtures (see also 3.1.34).

**9.1.1.3** A pyrotechnic substance is a solid substance or a liquid substance, or a mixture of substances, designed to produce an effect by heat, light, sound, gas or smoke, or a combination of these, as the result of non-detonative self-sustaining exothermic chemical reactions (see also 3.1.67).

**9.1.1.4** A pyrotechnic article is an article containing one or more pyrotechnic substances or mixtures (see also 3.1.66).

**9.1.1.5** The class of explosives comprises

- explosive substances and mixtures,
- explosive articles, with the exception of devices containing explosive substances or mixtures in such quantity or of such a character that their inadvertent or accidental ignition or initiation does not cause any effect external to the device either by projection, fire, smoke, heat or loud noise, and
- substances, mixtures and articles not mentioned under (a) and (b) above which are manufactured with a view to producing a practical, explosive or pyrotechnic effect.

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### **9.1.2 Classification criteria**

**9.1.2.1** Substances, mixtures and articles of this class that are not classified as an unstable explosive (see 3.1.36) are assigned to one of six divisions depending on the type of hazard they represent:

a) **division 1.1** – substances, mixtures and articles that present a mass explosion hazard;

NOTE A mass explosion is one that affects the entire quantity present virtually instantaneously.

b) **division 1.2** – substances, mixtures and articles that present a projection hazard but not a mass explosion hazard;

c) **division 1.3** – substances, mixtures and articles that present a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard:

1) combustion of which gives rise to considerable radiant heat; or

2) which burn one after another, producing minor blast or projection effects (or both);

d) **division 1.4** – substances, mixtures and articles that present:

1) no significant hazard; and

2) only a small hazard in the event of ignition or initiation. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire shall not cause virtually instantaneous explosion of almost the entire contents of the package;

e) **division 1.5** – very insensitive substances or mixtures that present a mass explosion hazard, but are so insensitive that there is very little probability of initiation or of transition from burning to detonation under normal conditions; and

f) **division 1.6** – extremely insensitive articles that do not present a mass explosion hazard and the probability of accidental initiation or propagation is negligible.

NOTE The risk of explosion is limited to a single article.

**9.1.2.2** Explosives, other than unstable explosives, are classified in one of the six divisions in accordance with Test Series 2 to Test Series 8 in Part I of the United Nations' *Recommendations on the transport of dangerous goods, Manual of tests and criteria* (see also SANS 10228).

### **9.1.3 Hazard communication**

The label elements applicable to explosives are given in table 4. See also:

a) clause 6 for general and specific considerations concerning labelling;

b) annex A, *Allocation of label elements*; and

c) annex B, *Hazard communication and classification summary tables*.

**Table 4 — Label elements for explosives**

1	2	3	4
Division	Symbol	Signal word	Hazard statement
Unstable explosive	Exploding bomb	Danger	Unstable explosive
1.1	Exploding bomb	Danger	Explosive; mass explosion hazard
1.2	Exploding bomb	Danger	Explosive; severe projection hazard
1.3	Exploding bomb	Danger	Explosive; fire, blast or projection hazard
1.4	Exploding bomb	Warning	Fire or projection hazard
1.5	No symbol; 1.5 on an orange background	Danger	May mass explode in fire
1.6	No symbol; 1.6 on an orange background	No signal word	No hazard statement

## 9.2 Flammable gases

### 9.2.1 Classification criteria

**9.2.1.1** A flammable gas (see 3.1.38) is classified in one of two categories as indicated in table 5.

NOTE See 9.3 for the classification of aerosols.

**Table 5 — Categories and classification criteria for flammable gases**

1	2
Category	Classification criteria
1	Gases that, at 20 °C and a standard pressure of 101,3 kPa: a) are ignitable when in a mixture of 13 % or less, by volume, in air; or b) have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit.
2	Gases that, at 20 °C and a standard pressure of 101,3 kPa , have a flammable range while mixed in air.

**9.2.1.2** The flammability of gases can be determined by tests or by calculations in accordance with ISO 10156. Where insufficient data are available to use these methods, tests by comparable methods recognized by the competent authority may be used.

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### 9.2.2 Hazard communication

The label elements applicable to flammable gases are given in table 6. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 6 — Label elements for flammable gases**

1	2	3	4
Category	Symbol	Signal word	Hazard statement
1	Flame	Danger	Extremely flammable gas
2	No symbol	Warning	Flammable gas

## 9.3 Flammable aerosols

### 9.3.1 Classification criteria

**9.3.1.1** An aerosol (see 3.1.2) shall be considered for classification as flammable if it contains any component classified as flammable in accordance with 9.2, 9.6 and 9.7.

**NOTE** Flammable components do not cover pyrophoric substances (see 9.9), self-heating substances (see 9.10) or water-reactive substances (see 9.11) as they are never used as contents for aerosols.

**9.3.1.2** A flammable aerosol is classified in one of two categories on the basis of its components, its chemical heat of combustion and, if applicable, of the results of the foam test (for foam aerosols), and of the ignition distance tests and the enclosed space test (for spray aerosols), in accordance with Part III, Section 31 of the United Nations' *Manual of tests and criteria*.

### 9.3.2 Hazard communication

The label elements applicable to flammable aerosols are given in table 7. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 7 — Label elements for flammable aerosols**

1	2	3	4
Category	Symbol	Signal word	Hazard statement
1	Flame	Danger	Extremely flammable aerosol
2	Flame	Warning	Flammable aerosol

## **9.4 Oxidizing gases**

### **9.4.1 Classification criteria**

**9.4.1.1** An oxidizing gas (see 3.1.61.1) is classified in a single category (see 9.4.2).

NOTE Artificial air containing up to 23,5 % oxygen, by volume, can be regarded as non-oxidizing for some regulatory purposes, for example transport.

**9.4.1.2** The oxidizing properties of a gas can be determined by tests or by calculations in accordance with ISO 10156 and ISO 10156-2.

### **9.4.2 Hazard communication**

The label elements for oxidizing gases, category 1, comprise the symbol of a flame over a circle, the signal word “Danger” and the hazard statement “May cause or intensify fire; oxidizer”. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

## **9.5 Gases under pressure**

### **9.5.1 General**

Gases under pressure are gases that are contained in a receptacle at a pressure not less than 280 kPa at 20 °C or as refrigerated liquids.

### **9.5.2 Classification criteria**

**9.5.2.1** Gases under pressure are classified in one of four groups according to their physical state when packaged:

- a) compressed gas – see 3.1.18;
- b) dissolved gas – see 3.1.28;
- c) liquefied gas – see 3.1.52; and
- d) refrigerated liquefied gas – see 3.1.69.

**9.5.2.2** The following data are required in order to classify gases under pressure:

- a) the vapour pressure at 50 °C;
- b) the physical state at 20 °C at a standard ambient pressure; and
- c) the critical temperature (see 3.1.22).

NOTE The data required for classification are available in literature, or can be calculated, or determined by testing. The classification of most pure gases is given in B.2 of SANS 10228:2006.

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### 9.5.3 Hazard communication

The label elements for gases under pressure are given in table 8. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 8 — Label elements for gases under pressure**

1	2	3	4
Group	Symbol	Signal word	Hazard statement
Compressed gas	Gas cylinder	Warning	Contains gas under pressure; may explode if heated
Dissolved gas	Gas cylinder	Warning	Contains gas under pressure; may explode if heated
Liquefied gas	Gas cylinder	Warning	Contains gas under pressure; may explode if heated
Refrigerated liquefied gas	Gas cylinder	Warning	Contains refrigerated gas; may cause cryogenic burns or injury

## 9.6 Flammable liquids

### 9.6.1 Classification criteria

**9.6.1.1** A flammable liquid is classified in one of four categories as indicated in table 9.

**Table 9 — Categories and classification criteria for flammable liquids**

1	2
Category	Classification criteria
1	Closed-cup flash point < 23 °C and initial boiling point ≤ 35 °C
2	Closed-cup flash point < 23 °C and initial boiling point > 35 °C
3	Closed-cup flash point ≥ 23 °C and ≤ 60 °C
4	Closed-cup flash point > 60 °C ≤ 93 °C

**9.6.1.2** For classification purposes, flammable liquids shall be tested in accordance with the test methods given in annex A of SANS 10228:2006.

**9.6.1.3** A non-toxic, non-corrosive liquid that has a closed-cup flash point of more than 35 °C and that does not sustain combustion can be regarded as non-flammable for transport under certain conditions (see SANS 10228).

**9.6.1.4** Paints, varnishes, enamels, adhesives, polishes and other viscous flammable liquids are regarded as a special group for transport (see SANS 10228).

### 9.6.2 Hazard communication

The label elements for flammable liquids are given in table 10. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 10 — Label elements for flammable liquids**

1	2	3	4
Category	Symbol	Signal word	Hazard statement
1	Flame	Danger	Extremely flammable liquid and vapour
2	Flame	Danger	Highly flammable liquid and vapour
3	Flame	Warning	Flammable liquid and vapour
4	No symbol required	Warning	Combustible liquid

## 9.7 Flammable solids

### 9.7.1 Classification criteria

**9.7.1.1** Solids (see 3.1.29 and 3.1.80) are classified in one of two categories as indicated in table 11.

**9.7.1.2** A preliminary screening test and a burning rate test (see annex A of SANS 10228:2006) shall be carried out for classification purposes. The tests shall be performed on the substance or mixture as presented. For example, a substance or mixture shall be retested if the same chemical is presented for supply or transport in a physical form different from that which was tested, and which is considered likely to alter the performance of the substance or mixture.

**9.7.1.3** Solids that can cause fire through friction shall be classified in this hazard class by analogy, for example matches, until definitive criteria are established.

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**Table 11 — Categories and classification criteria for flammable solids**

1	2
Category	Classification criteria (Burning rate test)
1	<p>a) <u>Substances or mixtures other than metal powders</u>: burning time &lt; 45 s or burning rate &gt; 2,2 mm/s, and the wetted zone does not stop flame propagation for at least 4 min.</p> <p>b) <u>Metal powders</u>: burning time ≤ 5 min.</p>
2	<p>a) <u>Substances or mixtures other than metal powders</u>: burning time &lt; 45 s or burning rate &gt; 2,2 mm/s, and the wetted zone stops flame propagation for at least 4 min.</p> <p>b) <u>Metal powders</u>: burning time &gt; 5 min and ≤ 10 min.</p>

### 9.7.2 Hazard communication

The label elements for flammable solids are given in table 12. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 12 — Label elements for flammable solids**

1	2	3	4
Category	Symbol	Signal word	Hazard statement
1	Flame	Danger	Flammable solid
2	Flame	Warning	Flammable solid

## 9.8 Self-reactive substances and mixtures

### 9.8.1 Properties

**9.8.1.1** The decomposition of self-reactive substances or mixtures can be initiated by friction, impact or heat, or by contact with catalytic impurities, for example acids, heavy metal compounds and heavy metal bases.

**9.8.1.2** The rate of decomposition increases with temperature and varies with the substance or mixture. Decomposition, particularly if no ignition occurs, can result in the evolution of toxic gases or vapours. In the case of certain self-reactive substances, the temperature has to be controlled. Some self-reactive substances or mixtures can decompose explosively, particularly if confined; this characteristic can be modified by the addition of diluents or by the use of appropriate packaging.



**9.8.1.3** Some self-reactive substances or mixtures burn vigorously. Self-reactive substances include some of the following types of compounds:

- a) aliphatic azo compounds ( $\text{-C-N=N-C-}$ );
- b) organic azides ( $\text{-C-N}_3$ );
- c) diazonium salts ( $\text{CN}_2^+\text{Z}^-$ );
- d) N-nitroso compounds ( $\text{-N-N=O}$ ); and
- e) aromatic sulfohydrazides ( $\text{SO}_2\text{-NH-NH}_2$ ).

## **9.8.2 Classification criteria**

### **9.8.2.1 General**

**9.8.2.1.1** A self-reactive substance or mixture shall be tested in accordance with test series A to H as described in Part II of the United Nations' *Manual of tests and criteria*.

**9.8.2.1.2** A substance or mixture is not considered self-reactive (see 3.1.74) when:

- a) it is an explosive (see 9.1);
- b) it is an oxidizing liquid or solid (see 9.12), except that a mixture of oxidizing substances that contains 5 % or more of combustible organic substances shall be classified as a self-reactive substance in accordance with the procedure given in note 1 to 9.8.2.2;
- c) it is an organic peroxide (see 9.13);
- d) the heat of decomposition is less than 300 J/g; and

NOTE The heat of decomposition can be determined by means of any internationally recognized method, for example differential scanning calorimetry or adiabatic calorimetry.

- e) the self-accelerating decomposition temperature (SADT) (see 3.1.72) is greater than 75 °C for a 50 kg package.

### **9.8.2.2 Types of self-reactive substances or mixtures**

Self-reactive substances or mixtures are classified in one of seven types, in accordance with the danger they present:

- a) **type A** – a substance or mixture that can detonate or deflagrate rapidly, as packaged;
- b) **type B** – a substance or mixture that has explosive properties, and that, as packaged, neither detonates or deflagrates rapidly, but is liable to undergo a thermal explosion in that package;
- c) **type C** – a substance or mixture that has explosive properties but, as packaged, cannot detonate or deflagrate rapidly or undergo a thermal explosion;
- d) **type D** – a substance or mixture that, during laboratory testing, and as packaged,
  - 1) detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement, or

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- 2) does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement, or
- 3) does not detonate or deflagrate at all and shows a medium effect when heated under confinement;
- e) **type E** – a substance or mixture that, during laboratory testing, neither detonates nor deflagrates at all and shows little or no effect when heated under confinement, or
- f) **type F** – a substance or mixture that, during laboratory testing, neither detonates in the cavitated state nor deflagrates at all, shows little or no effect when heated under confinement, and shows low or no explosive power, or
- g) **type G** – a substance or mixture that, during laboratory testing, neither detonates in the cavitated state nor deflagrates at all, shows little or no effect when heated under confinement, and shows no explosive power. However, the substance or mixture shall be thermally stable with a SADT (see 3.1.72) of 60 °C to 75 °C for a 50 kg package and a liquid mixture shall be desensitized with a diluent (see 3.1.27) of boiling point not less 150 °C.

NOTE 1 A mixture of oxidizing substances meeting the criteria for classification as an oxidizing substance, and that contains 5 % or more of combustible organic substances and that does not meet the criteria given in (a), (c), (d) or (e) above, shall be subjected to the self-reactive substances classification procedure.

NOTE 2 Types A to G might not be necessary for all systems.

### 9.8.2.3 Criteria for temperature control

A self-reactive substance shall be subjected to temperature control if its SADT is less than or equal to 55 °C. The SADT as well as the derivation of the control temperature (see 3.1.20) and the emergency temperature (see 3.1.32) shall be determined in accordance with the test methods given in Part II, Section 28 of the United Nations' *Manual of tests and criteria*.

### 9.8.3 Hazard communication

The label elements for self-reactive substances or mixtures are given in table 13. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 13 — Label elements for self-reactive substances**

1	2	3	4
Type	Symbol	Signal word	Hazard statement
A	Exploding bomb	Danger	Heating may cause an explosion
B	Exploding bomb	Danger	Heating may cause a fire or explosion
C and D	Flame	Danger	Heating may cause a fire
E and F	Flame	Warning	Heating may cause a fire
G	No label elements assigned <sup>a</sup>		
<sup>a</sup> Label elements applicable to relevant properties of other hazard classes to be considered.			

## **9.9 Pyrophoric substances**

### **9.9.1 Classification criteria**

#### **9.9.1.1 Pyrophoric liquids**

A pyrophoric liquid (see 3.1.65) shall be tested in accordance with the relevant test methods as given in annex A of SANS 10228:2006 and classified in a single category in compliance with the following criteria:

**category 1** – the liquid ignites within 5 min when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min.

#### **9.9.1.2 Pyrophoric solids**

**9.9.1.2.1** A pyrophoric solid (see 3.1.65) shall be tested in accordance with the relevant test methods as given in annex A of SANS 10228:2006 and classified in a single category in compliance with the following criterion:

**category 1** – the solid ignites within 5 min of coming into contact with air.

**9.9.1.2.2** The classification test on solid substances and mixtures shall be performed on the substance or mixture as presented. If the same chemical is to be presented, for supply or transport, in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance shall be retested in the new form.

**NOTE** The test procedure for a pyrophoric liquid or solid need not be applied when experience in production or handling shows that the substance or mixture does not ignite spontaneously on coming in contact with air at normal temperatures, that is, the substance is known to be stable at room temperature for prolonged periods of time (days).

#### **9.9.1.3 Hazard communication**

The label elements for pyrophoric liquids or solids, category 1, comprise the symbol of a flame, the signal word “Danger” and the hazard statement “Catches fire spontaneously if exposed to air”. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

## **9.10 Self-heating substances and mixtures**

### **9.10.1 Properties**

Self-heating of substances or mixtures is caused by reaction of the substance or mixture with oxygen in the air and when the heat that develops is not conducted away rapidly enough to the surroundings. Spontaneous combustion occurs when the rate of heat production exceeds the rate of heat loss and the auto-ignition temperature is reached. Some substances can emit toxic gases when they are involved in a fire. See also 3.1.73.

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### 9.10.2 Classification criteria

**9.10.2.1** A substance or mixture shall be classified as a self-heating substance or mixture of category 1 or 2 when, tested in accordance with the relevant test method given in annex A of SANS 10228:2006, the results as given in column 2 of table 14 are obtained.

**Table 14 — Categories and classification criteria for self-heating substances**

1	2
Category	Classification criteria
1	A positive result is obtained in a test using a 25 mm specimen cube at 140 °C.
2	<p>a) A positive result is obtained in a test using a 25 mm specimen cube at 140 °C and a negative result is obtained when using a 100 mm specimen cube, and the substance or mixture is to be packed in packages with a volume of more than 3 m<sup>3</sup>; or</p> <p>b) a positive result is obtained in a test using a 100 mm specimen cube at 140 °C and a negative result is obtained in a test using a 25 mm specimen cube at 140 °C, a positive result is obtained in a test using a 100 mm specimen cube at 120 °C, and the substance or mixture is to be packed in packages with a volume of more than 450 L; or</p> <p>c) a positive result is obtained in a test using a 100 mm specimen cube at 140 °C and a negative result is obtained in a test using a 25 mm specimen cube at 140 °C, and a positive result is obtained in a test using a 100 mm specimen cube at 100 °C.</p>

**9.10.2.2** The tests shall be performed on solid substances or mixtures as presented. If the same chemical is to be presented, for supply or transport, in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance shall be retested in the new form.

**9.10.2.3** The classification criteria for self-heating substances are based on the self-ignition temperature of charcoal, which is 50 °C for a specimen cube of 27 m<sup>3</sup>. Substances and mixtures with a temperature of spontaneous combustion higher than 50 °C for a volume of 27 m<sup>3</sup> shall not be assigned to this hazard class. Additionally, substances and mixtures with a spontaneous ignition temperature higher than 50 °C for a volume of 450 L shall not be assigned to category 1.

### 9.10.3 Hazard communication

The label elements for self-heating substances or mixtures are given in table 15. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 15 — Label elements for self-heating substances and mixtures**

1	2	3	4
Category	Symbol	Signal word	Hazard statement
1	Flame	Danger	Self-heating; may catch fire
2	Flame	Warning	Self-heating in large quantities; may catch fire

## 9.11 Substances and mixtures that, on contact with water, emit flammable gases

### 9.11.1 General

Certain substances, on contact with water, emit flammable gases that can form explosive mixtures with air. Such gas mixtures are easily ignited by ordinary sources of ignition, for example naked flames, sparking hand tools or unprotected light bulbs. The resulting blast wave and flames can endanger people and the environment.

### 9.11.2 Classification criteria

**9.11.2.1** A substance or mixture that, on contact with water, emits flammable gases is classified in one of three categories if, when tested in accordance with SANS 10228, the results as given in column 2 of table 16 are obtained.

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**Table 16 — Categories and classification criteria for substances that, on contact with water, emit flammable gases**

1	2
Category	Classification criteria <sup>a</sup>
1	A substance or mixture that reacts: <ul style="list-style-type: none"> <li>a) violently with water at ambient temperature with a general tendency for the gas evolved to ignite spontaneously; or</li> <li>b) readily with water at ambient temperature such that the rate of evolution of flammable gas is equal to or exceeds 10 L/kg of the substance under test in any 1 min.</li> </ul>
2	A substance or mixture that: <ul style="list-style-type: none"> <li>a) reacts readily with water at ambient temperature such that the rate of evolution of flammable gas is equal to or exceeds 20 L/kg of substance under test per hour, and</li> <li>b) does not meet the criteria for category 1.</li> </ul>
3	A substance or mixture that: <ul style="list-style-type: none"> <li>a) reacts slowly with water at ambient temperature such that the rate of evolution of flammable gas is equal to or exceeds 1 L/kg of substance under test per hour; and</li> <li>b) does not meet the criteria for categories 1 and 2.</li> </ul>
<sup>a</sup> A substance or mixture is classified as a substance that, on contact with water, emits flammable gases if spontaneous ignition occurs in any step of the test procedure.	

**9.11.2.2** The classification tests on solid substances and mixtures shall be performed on a substance or a mixture as presented. If the same chemical is to be presented, for supply or transport, in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance shall be retested in the new form.

**9.11.2.3** The classification procedure need not be applied if:

- a) the chemical structure of the substance or mixture does not contain metals or metalloids;
- b) experience in production or handling shows that the substance or mixture does not react with water, for example the substance is manufactured with water or washed with water; or
- c) the substance or mixture is known to be soluble in water to form a stable solution.

### 9.11.3 Hazard communication

The label elements for substances that, on contact with water, emit flammable gases are given in table 17. See also:

- a) clause 6 for general and specific considerations concerning labelling;

b) annex A, *Allocation of label elements*; and

c) annex B, *Hazard communication and classification summary tables*.

**Table 17 — Label elements for substances and mixtures that, on contact with water, emits flammable gases**

1	2	3	4
Category	Symbol	Signal word	Hazard statement
1	Flame	Danger	In contact with water releases flammable gases that may ignite spontaneously
2	Flame	Danger	In contact with water releases flammable gases
3	Flame	Warning	In contact with water releases flammable gases

## 9.12 Oxidizing substances and mixtures

### 9.12.1 General

**9.12.1.1** Although oxidizing substances (see 3.1.61) are not necessarily combustible, they can, either by yielding oxygen or by similar processes cause, or contribute to, the combustion of other materials with which they come into contact.

**9.12.1.2** Depending on the amount and nature of combustible impurities they might contain, certain oxidizing substances are sensitive to impact, friction or a rise in temperature.

**9.12.1.3** Some mixtures of oxidizing substances and combustible material, for example hydrocarbons are so readily ignited that friction or impact can cause ignition. Such a mixture can burn with explosive force.

**9.12.1.4** There will be a violent reaction between most oxidizing substances and strong liquid acids, resulting in the emission of highly toxic gases. Such gases can also be emitted when certain oxidizing substances are involved in a fire.

### 9.12.2 Classification criteria

#### 9.12.2.1 Oxidizing liquids

**9.12.2.1.1** An oxidizing liquid (see 3.1.61.2) is classified in one of three categories as indicated in table 18 when, tested in accordance with SANS 10228, the results as given in column 2 of table 18 are obtained.

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**Table 18 — Categories and classification criteria for oxidizing liquids**

1	2
Category	Classification criteria
1	<p>a) A substance or mixture that, in the 1:1 specimen-to-cellulose ratio, by mass, ignites spontaneously; or</p> <p>b) the mean pressure rise time of a 1:1 specimen-to-cellulose ratio, by mass, exhibits a mean pressure rise time less than that of a 1:1 mixture, by mass, of 50 % perchloric acid and cellulose.</p>
2	<p>a) A substance or mixture that, in the 1:1 specimen-to-cellulose ratio, by mass, exhibits a mean pressure rise time less than, or equal to, the mean pressure rise time of a 1:1 mixture, by mass, of a 40 % aqueous sodium chlorate solution and cellulose; and</p> <p>b) the criteria of category 1 are not met.</p>
3	<p>a) A substance or mixture that, in the 1:1 specimen-to-cellulose ratio, by mass, exhibits a mean pressure rise time less than, or equal to, the mean pressure rise time of a 1:1 mixture, by mass, of 65 % aqueous nitric acid and cellulose; and</p> <p>b) the criteria for category 1 and 2 are not met.</p>

**9.12.2.1.2** The classification procedure need not be applied for:

a) organic substances or mixtures if

- 1) the substances or mixtures do not contain oxygen, fluorine or chlorine atoms, or
- 2) the substances or mixtures contain oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen; and

b) inorganic substances or mixtures if they do not contain oxygen or halogen atoms.

### **9.12.2.2 Oxidizing solids**

**9.12.2.2.1** An oxidizing solid (see 3.1.61.3) is classified in one of three categories as indicated in table 19 if, when tested in accordance with SANS 10228, the results as given in column 2 of table 19 are obtained.



**Table 19 — Categories and classification criteria for oxidizing solids**

1	2
Categories	Classification criteria
1	A substance or mixture that, in the 4:1 or 1:1 specimen-to-cellulose ratio, by mass, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate-to cellulose ratio, by mass.
2	a) A substance or mixture that, in the 4:1 or 1:1 specimen-to-cellulose ratio, by mass, exhibits a mean burning time equal to or less than the mean burning time of a 3:2 potassium bromate-to cellulose ratio, by mass; and b) the criteria of category 1 are not met.
3	a) A substance or mixture that, in the 4:1 or 1:1 specimen-to-cellulose ratio, by mass, exhibits a mean burning time equal to or less than the mean burning time of a 3:7 potassium bromate-to cellulose ratio, by mass; and b) the criteria of categories 1 and 2 are not met.

**9.12.2.2.2** The classification tests on solid substances or mixtures shall be performed on the substance or mixture as presented. If the same chemical is to be presented, for supply or transport, in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance shall be retested in the new form.

**9.12.2.2.3** The classification procedure need not be applied to solid organic and inorganic substances and mixtures if the requirements of 9.12.2.2.2 are met.

### **9.12.3 Hazard communication**

The label elements for oxidizing solid and oxidizing liquid substances and mixtures are given in table 20. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 20 — Label elements for oxidizing liquids and solids**

1	2	3	4
Category	Symbol	Signal word	Hazard statement
1	Flame over circle	Danger	May cause fire or explosion; strong oxidizer
2	Flame over circle	Danger	May intensify fire; oxidizer
3	Flame over circle	Warning	May intensify fire; oxidizer

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### **9.13 Organic peroxides**

#### **9.13.1 General**

**9.13.1.1** Organic peroxides are liquid or solid organic substances that contain the bivalent -O-O- structure and can be considered derivatives of hydrogen peroxide where one, or both, of the hydrogen atoms has been replaced by organic radicals (see also 3.1.60).

**9.13.1.2** Organic peroxides are thermally unstable substances or mixtures that can undergo exothermic decomposition at normal or elevated temperatures. The decomposition can be initiated by heat, friction, impact or contact with impurities, for example acids, heavy metal compounds and amines. The rate of decomposition increases with a rise in temperature and can vary with different formulations (mixtures) of the same organic peroxide.

**9.13.1.3** Most organic peroxides burn rapidly and decomposition of the substance or mixture can result in the evolution of harmful, or flammable, gases and vapours.

**9.13.1.4** Contact of organic peroxides with the eyes and skin should be avoided since they can cause serious injury to the cornea even after brief contact, and they can be corrosive to skin.

**9.13.1.5** An organic peroxide is regarded as possessing explosive properties when, in laboratory testing, the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

#### **9.13.2 Classification criteria**

An organic peroxide shall not be considered for classification in this class if it contains:

1,0 % (or less) of available oxygen derived from the organic peroxide and 1,0 % (or less) of hydrogen peroxide; or

0,5 % (or less) of available oxygen derived from organic peroxide and more than 1,0 %, but not more than 7,0 % of hydrogen peroxide.

NOTE The available oxygen content (%) of an organic peroxide formulation (mixture) is given by the formula

$$16 \times \sum_i^n \left( \frac{n_i \times c_i}{m_i} \right)$$

where

$n_i$  is the number of peroxygen groups per molecule of organic peroxide  $i$ ;

$c_i$  is the concentration in percentage by mass of organic peroxide  $i$ ;

$m_i$  is the molecular mass of organic peroxide  $i$ .

### 9.13.3 Types of organic peroxides

Organic peroxides are classified in one of seven categories, in accordance with the danger they present:

- a) **type A** – an organic peroxide that can detonate or deflagrate rapidly, as packaged;
- b) **type B** – an organic peroxide that has explosive properties, and that, as packaged, neither detonates or deflagrates rapidly, but is liable to undergo a thermal explosion in that package;
- c) **type C** – an organic peroxide that has explosive properties but, as packaged, cannot detonate or deflagrate rapidly or undergo a thermal explosion;
- d) **type D** – an organic peroxide that, during laboratory testing, and as packaged,
  - 1) detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement, or
  - 2) does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement, or
  - 3) does not detonate or deflagrate at all and shows a medium effect when heated under confinement;
- e) **type E** – an organic peroxide that, during laboratory testing, neither detonates nor deflagrates at all and shows little or no effect when heated under confinement, or
- f) **type F** – an organic peroxide that, during laboratory testing, neither detonates in the cavitated state nor deflagrates at all, shows little or no effect when heated under confinement, and shows low or no explosive power, or
- g) **type G** – an organic peroxide that, during laboratory testing, neither detonates in the cavitated state nor deflagrates at all, shows little or no effect when heated under confinement, and shows no explosive power. However, the substance or mixture shall be thermally stable with a SADT (see 3.1.72) of 60 °C to 75 °C for a 50 kg package and a liquid mixture shall be desensitized with a diluent (see 3.1.27) of boiling point not less 150 °C.

### 9.13.4 Criteria for temperature control

**9.13.4.1** The following organic peroxides need to be subjected to temperature control:

- a) organic peroxides types B and C with an SADT less than or equal to 50 °C;
- b) organic peroxide type D that shows a medium effect when heated under confinement with an SADT less than or equal to 50 °C, or showing a low, or no effect, when heated under confinement with an SADT of less than or equal to 45 °C; and
- c) organic peroxides types E and F with an SADT of less than or equal to 45 °C.

**9.13.4.2** The test methods for determining the SADT as well as the derivation of control and emergency temperatures are given in the United Nations' *Manual of test and criteria*. The test selected shall be conducted in a manner that is representative, both in size and material, of the package.

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### 9.13.5 Hazard communication

The label elements for organic peroxides are given in table 21. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 21 — Label elements for organic peroxides**

1	2	3	4
Type	Symbol	Signal word	Hazard statement
A	Exploding bomb	Danger	Heating may cause an explosion
B	Exploding bomb	Danger	Heating may cause a fire or explosion
C and D	Flame	Danger	Heating may cause a fire
E and F	Flame	Warning	Heating may cause a fire
G	No label elements assigned <sup>a</sup>		
<sup>a</sup> Label elements applicable to relevant properties of other hazard classes to be considered.			

## 9.14 Corrosive to metals

### 9.14.1 Classification criteria

A substance or a mixture that is corrosive to metal (see 3.1.21) shall be tested in accordance with SANS 10228 and classified in a single category when it complies with the following criteria:

**category 1** – the corrosion rate on steel or aluminium surfaces exceeds 6,25 mm/year at a test temperature of 55 °C.

NOTE Suitable metals are steel, grade 240 WA of SANS 1431 (or a similar type) and aluminium, non clad type 7075-T6 or AZ5GU T6 (ASTM G31).

### 9.14.2 Hazard communication

The label elements for substances or mixtures comprise the “Corrosive” symbol (see figure 1), the signal word “Warning” and the hazard statement “May be corrosive to metals”. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

## **10 Health hazards**

### **10.1 Acute toxicity**

#### **10.1.1 Classification criteria for substances**

**10.1.1.1** Chemical substances can be allocated to one of five acute toxicity hazard categories based on acute toxicity by the oral, dermal or inhalation route in accordance with the numeric cut-off values as shown in table 22. Acute toxicity values are expressed as (approximate)  $LD_{50}$  (oral, dermal) or  $LC_{50}$  (inhalation) values or as acute toxicity estimates (ATE) (see notes to table 22).

**10.1.1.2** Test data already generated for the classification of chemicals under existing systems should be accepted when reclassifying these chemicals under the harmonized system.

**10.1.1.3** The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity. When experimental data for acute toxicity are available in several animal species, scientific judgement should be used in selecting the most appropriate  $LD_{50}$  value from among valid, well-performed tests.

**10.1.1.4** The acute toxicity values for hazard category 1 (see table 22), the highest toxicity category, are used primarily by the transport sector for the allocation of packing groups (see SANS 10228).

**10.1.1.5** Hazard category 5 is applicable to chemicals that are of relatively low acute toxicity but which, under certain circumstances, may pose a hazard to vulnerable populations.

**NOTE** Recognizing the need to protect animal welfare, animal testing in category 5 ranges is discouraged and should only be considered when there is a strong likelihood that results of such a test would have a direct relevance for protecting human health.

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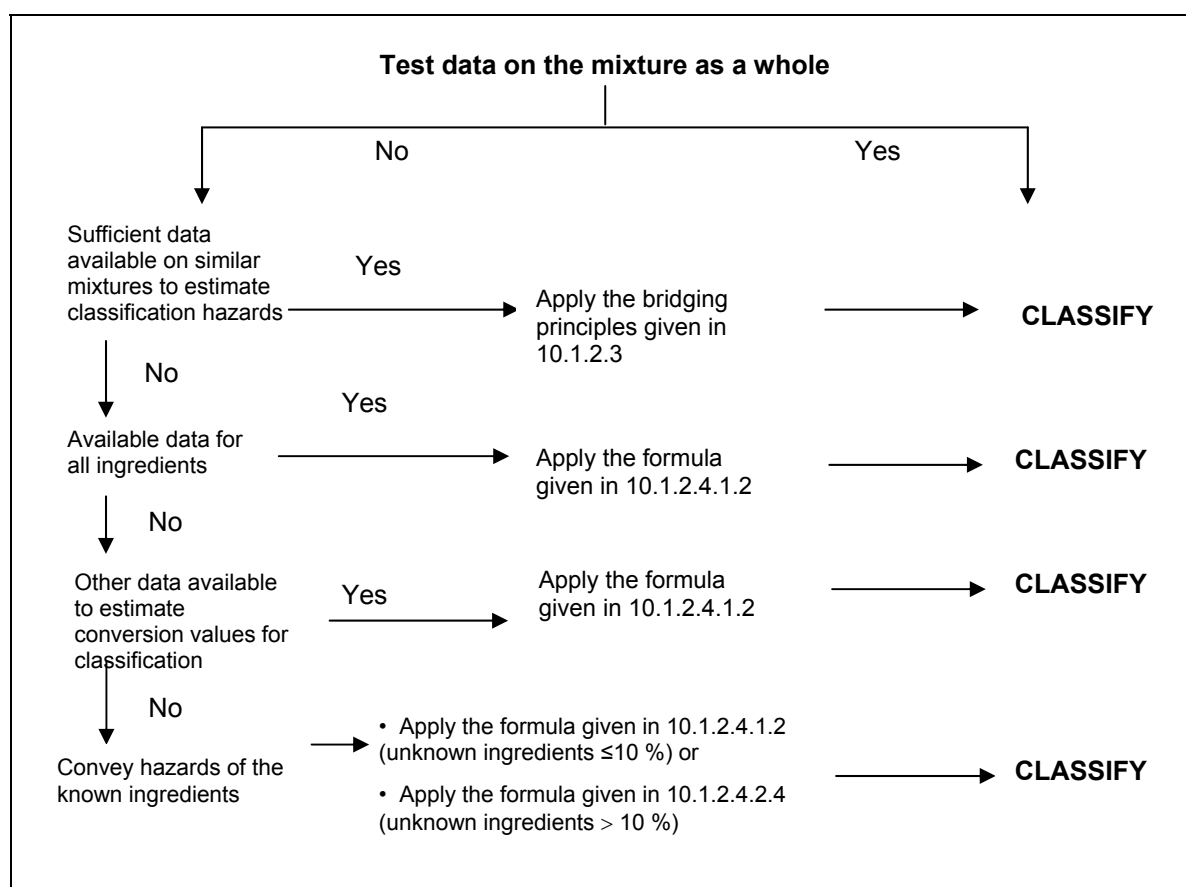
**Table 22 — Acute toxicity hazard categories and acute toxicity estimate (ATE) values**

1	2	3	4	5	6
Routes of exposure	Category 1	Category 2	Category 3	Category 4	Category 5
<b>Oral</b> ( <i>LD</i> <sub>50</sub> expressed as mg/kg bodyweight) (see Note 1)	5	50	300	2 000	5 000  (See note 6)
<b>Dermal</b> ( <i>LD</i> <sub>50</sub> expressed as mg/kg bodyweight) (see Note 1)	50	200	1 000	2 000	
<b>Gases</b> ( <i>LC</i> <sub>50</sub> expressed as ppmV) <sup>a</sup> (see Notes 1 and 2)	100	500	2 500	5 000	
<b>Vapours</b> ( <i>LC</i> <sub>50</sub> expressed as mg/L) (see Notes 1, 2, 3 and 4)	0,5	2,0	10	20	
<b>Dusts and mists</b> ( <i>LC</i> <sub>50</sub> expressed as mg/L) (see Notes 2 and 5)	0,05	0,5	1,0	5	
NOTE 1 The acute toxicity estimate (ATE) for the classification of a substance or an ingredient in a mixture is derived by using:  a) the <i>LD</i> <sub>50</sub> / <i>LC</i> <sub>50</sub> where available;  b) the appropriate conversion value from table 23 that relates to the results of a range test; or  c) the appropriate conversion value from table 23 that relates to a classification category.  NOTE 2 The criteria for acute inhalation toxicity are based on <i>LC</i> <sub>50</sub> data relating to exposures of 4 h and where such information is available it shall be used for the classification of a substance. However, where only <i>LC</i> <sub>50</sub> data relating to 1 h are available, such values can be divided by 2 for gases and vapours, and by 4 for dusts and mists.  NOTE 3 The saturated vapour concentration (see SANS 10228) of a chemical is used by the transport sector for the allocation of packing groups (see 10229-1).  NOTE 4 For some chemicals the test atmosphere will not just be a vapour but will consist of a mixture of liquid and vapour phases. For other chemicals the test atmosphere may consist of a vapour that is near the gaseous phase. In these cases, classification shall be based on ppmV.  NOTE 5 The values for dusts and mists should be reviewed to take into account any changes to the OECD Test Guidelines (see annex J) with respect to technical limitation in generating, maintaining and measuring dust and mist concentrations in respirable form.  NOTE 6 The criteria for category 5 are intended to enable the identification of substances that are of relatively low acute toxicity hazard. However, under certain circumstances they may present a danger to vulnerable populations. These substances are anticipated to have an oral or dermal toxicity ( <i>LD</i> <sub>50</sub> ) in the range of 2 000 mg/kg to 5 000 mg/kg bodyweight and equivalent doses for inhalation. The specific criteria for category 5 are:  a) reliable evidence indicates the <i>LD</i> <sub>50</sub> (or <i>LC</i> <sub>50</sub> ) to be in the range of category 5 values, or other animal studies or toxic effects in humans indicate a concern for human health of an acute nature; and  b) extrapolation, estimation or experimental data indicates that assignment to category 1, 2, 3 or 4 is not warranted, and provided:  1) reliable information is available indicating significant toxic effects in humans; or  2) any mortality is observed when tested up to category 4 values by the oral, dermal or inhalation routes; or  3) expert judgement confirms significant clinical evidence of toxicity when tested up to category 4 values, with the exception of diarrhoea, piloerection or an ungroomed appearance; or  4) expert judgement confirms reliable information indicating the potential for significant acute effects from other animal studies.					
<sup>a</sup> The concentration of a gas is expressed in parts per million per volume (ppmV).					

## 10.1.2 Classification criteria for mixtures

### 10.1.2.1 General

**10.1.2.1.1** The classification of substances is based on lethal dose data (tested or derived). However, for the classification of mixtures it is necessary to obtain, or derive, information that allows the criteria to be applied to the mixture. A tiered approach to the evaluation of initial information should be followed where applicable, recognizing that all elements might not be relevant in certain cases. Flow chart 1 outlines the process to be followed for the classification of mixtures.



**Flow chart 1 — Tiered approach to classification of mixtures for acute toxicity**

**10.1.2.1.2** The classification of mixtures for acute toxicity can be carried out for each route of exposure but is only needed for one route of exposure, provided that the same route of exposure is followed for all the ingredients. If the acute toxicity is determined for more than one route of exposure, the more severe hazard category shall be used for classification. All available information should be considered and all relevant routes of exposure should be identified for hazard communication.

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**10.1.2.1.3** In order to make use of all available data for purposes of classifying a mixture, certain assumptions have been made and should be applied where appropriate in the tiered approach:

- a) the ingredients relevant for the classification of a mixture are the ingredients present in concentrations greater than or equal to 1 %, (by mass for solids, liquids, dusts, mists and vapours, and by volume for gases). However, an ingredient present at a concentration of less than 1 % can be used for classification purposes if there is reason to suspect that the substance is relevant for the classification of the mixture for acute toxicity, in particular when untested mixtures contain ingredients that are classified in category 1 and category 2; and
- b) where a classified mixture is used as an ingredient of another mixture, the actual or derived acute toxicity estimate (ATE) for that mixture may be used when calculating the classification of the new mixture using the formulas in 10.1.2.4.1.2 and 10.1.2.4.2.4.



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**Table 23 — Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories), to acute toxicity point estimates for classification for the respective routes of exposure**

1	2	3
Routes of exposure	Experimentally obtained acute toxicity range values, or acute toxicity classification category	Converted acute toxicity point estimate (see Note 2)
<b>Oral</b> ( $LD_{50}$ expressed as mg/kg bodyweight )	Category 1 $\leq 5$ Category 2 $> 5 \leq 50$ Category 3 $> 50 \leq 300$ Category 4 $> 300 \leq 2\,000$ Category 5 $< 2\,000 \leq 5\,000$ (see Note 1)	0,5 5 100 500 2 500
<b>Dermal</b> ( $LD_{50}$ expressed as mg/kg bodyweight)	Category 1 $\leq 50$ Category 2 $< 50 \leq 200$ Category 3 $< 200 \leq 1\,000$ Category 4 $> 1\,000 \leq 2\,000$ Category 5 $< 2\,000 \leq 5\,000$ (see Note 1)	5 50 300 1 100 2 500
<b>Gases</b> ( $LC_{50}$ expressed as ppmV)	Category 1 $\leq 100$ Category 2 $> 100 \leq 500$ Category 3 $> 500 \leq 2\,500$ Category 4 $> 2\,500 \leq 5\,000$ Category 5 (see Note 5 to table 22)	10 100 700 3 000 –
<b>Vapours</b> ( $LC_{50}$ expressed as mg/l)	Category 1 $\leq 0,5$ Category 2 $> 0,5 \leq 2,0$ Category 3 $> 2,0 \leq 10,0$ Category 4 $> 10 \leq 20,0$ Category 5 (see Note 5 to table 22)	0,05 0,5 3 11 –
<b>Dusts and mists</b> ( $LC_{50}$ expressed as mg/l)	Category 1 $\leq 0,05$ Category 2 $> 0,05 \leq 0,5$ Category 3 $> 0,5 \leq 1,0$ Category 4 $> 1,0 \leq 5,0$ Category 5 (see Note 5 to table 22)	0,005 0,05 0,5 1,5 –

NOTE 1 Category 5 is applicable to mixtures that are of relatively low acute toxicity but, under certain circumstances, may pose a hazard to vulnerable populations. These mixtures are anticipated to have an oral or dermal  $LD_{50}$  value in the range of 2 000 mg/kg to 5 000 mg/kg bodyweight or equivalent dose for other routes of exposure. In light of animal welfare considerations, testing in animals in category 5 ranges is discouraged and should only be considered when there is a strong likelihood that results of such testing would have a direct relevance for protecting human health.

NOTE 2 These values are designed to be used in the calculation of the ATE for the classification of a mixture based on its components and do not represent test results. The values are conservatively set at the lower end of the range of categories 1 and 2, and at a point approximately one tenth from the lower end of the range for category 3 to category 5.

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### **10.1.2.2 Classification of mixtures where acute toxicity test data are available for the complete mixture**

Where the mixture itself has been tested to determine its acute toxicity, it shall be classified according to the same criteria as those used for substances (see table 22).

### **10.1.2.3 Classification of mixtures where acute toxicity test data are not available for the complete mixture: Bridging principles**

#### **10.1.2.3.1 General**

Where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the bridging principles given in 10.1.2.3.2 to 10.1.2.3.7. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional animal testing.

#### **10.1.2.3.2 Dilution**

If a mixture is diluted with a substance that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then the new mixture may be classified as equivalent to the original mixture. Alternatively, the formula given in 10.1.2.4.1.2 can be applied.

If a mixture is diluted with water or other non-toxic material, the toxicity of the mixture can be calculated from test data on the undiluted mixture. For example, if a mixture with an  $LD_{50}$  of 1 000 mg/kg bodyweight were diluted with an equal volume of water, the  $LD_{50}$  of the diluted mixture would be 2 000 mg/kg bodyweight.

#### **10.1.2.3.3 Batching**

The toxicity of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by, or under the control of, the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the batch has changed. If the latter occurs, a new classification is necessary.

#### **10.1.2.3.4 Concentration of highly toxic mixtures**

If a mixture is classified in category 1, and the concentration of the ingredients of the mixture that are in category 1 is increased, the new mixture shall be classified in category 1 without additional testing.

#### **10.1.2.3.5 Interpolation within one toxicity category**

For three mixtures, A, B and C with identical ingredients, where A and B are in the same toxicity category and mixture C has the same toxicologically active ingredients with concentrations intermediate to the concentrations of those ingredients in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.

#### **10.1.2.3.6 Substantially similar mixtures**

In the case of two mixtures (A+B) and (C+B) where

- a) the concentration of ingredient B is essentially the same in both mixtures,
  - b) the concentration of ingredient A equals that of ingredient C,
  - c) the toxicity data for ingredient A and ingredient C are available and substantially equivalent, that is, they are in the same hazard category and are not expected to affect the toxicity of B, and
  - d) mixture (A+B) has already been classified based on test data,
- then mixture (C+B) can be assigned the same hazard category as that of mixture (A+B).

#### **10.1.2.3.7 Aerosols**

An aerosol form of a mixture can be classified in the same hazard category as the tested, non-aerosol form of the mixture for oral and dermal toxicity, provided that the added propellant does not affect the toxicity of the mixture on spraying.

NOTE The inhalation toxicity of an aerosol form mixture should be considered separately.

#### **10.1.2.4 Classification of mixtures based on ingredients of the mixture (Additivity formula)**

##### **10.1.2.4.1 Data are available for all ingredients**

**10.1.2.4.1.1** In order to ensure that the classification of the mixture is accurate, and that the calculation need only be performed once for all systems, sectors, and categories, the ATE of the ingredients should be considered as follows:

- a) include the ingredients with a known acute toxicity which fall into any of the GHS acute toxicity categories;
- b) ignore the ingredients
  - 1) that are presumed not to be acutely toxic (for example, water, sugar), and
  - 2) if the oral limit test does not show an acute toxicity at 2 000 mg/kg bodyweight.

**10.1.2.4.1.2** The ingredients of the mixture that fall within the scope of this clause are considered to be ingredients with a known ATE.

The ATE of the mixture for oral, dermal or inhalation toxicity is determined by calculation from the ATE values for all relevant ingredients according to the following formula:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

where

$C$  is the concentration of the unknown ingredient;

$C_i$  is the concentration of ingredient  $i$ ;

$n$  is the number of ingredients and  $i$  is running from 1 to  $n$ ;

$ATE_i$  is the acute toxicity estimate of ingredient  $i$ .

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### 10.1.2.4.2 Data are not available for one or more ingredients of the mixture

**10.1.2.4.2.1** Where an ATE is not available for an individual ingredient of the mixture, but available information such as that listed below can provide a derived conversion value, the formula in 10.1.2.4.1.2 can be applied. Such available information can include the evaluation of:

a) extrapolation between oral, dermal and inhalation acute toxicity estimates. Such an evaluation could require appropriate pharmacodynamic and pharmacokinetic data;

**NOTE** For ingredients with ATEs available for exposure routes other than oral, dermal or inhalation toxicity, values can be extrapolated from the available exposure route to the most relevant route. Dermal and inhalation route data are not always required for ingredients. However, in a case where data requirements for specific ingredients include acute toxicity estimates for the dermal and inhalation route, the values to be used in the formula need to be from the required exposure route.

b) evidence from human exposure that indicates toxic effects but does not provide lethal dose data;

c) evidence from any other toxicity tests/assays available on the substance that indicates toxic acute effects but does not necessarily provide lethal dose data; or

d) data from closely analogous substances using structure/activity relationships.

This approach generally requires substantial supplemental technical information, and a highly trained and experienced expert, to reliably estimate acute toxicity. If such information is not available, proceed to the provisions of 10.1.2.4.2.4.

**10.1.2.4.2.2** In the event that an ingredient without any useable information at all is used in a mixture at a concentration of 1 % or more, it is concluded that the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture should be classified based on the known ingredients only, with the additional statement that “x” percent of the mixture consists of ingredient(s) of unknown toxicity.

**10.1.2.4.2.3** If the total concentration of the ingredient(s) with unknown acute toxicity is equal to or less than 10 %, by mass, then the formula presented in 10.1.2.4.1.2 should be used.

**10.1.2.4.2.4** If the total concentration of the ingredient(s) with unknown toxicity is greater than 10 %, by mass, the formula presented in 10.1.2.4.1.2 should be corrected to adjust for the total percentage of the unknown ingredient(s) as follows:

$$\frac{100 - \left( \sum C_{unknown} \text{ if } > 10\% \right)}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

where

$C$  is the concentration of the unknown ingredient;

$C_i$  is the concentration of ingredient  $i$ ;

$n$  is the number of ingredients and  $i$  is running from 1 to  $n$ ;

$ATE_i$  is the acute toxicity estimate of ingredient  $i$ .

### 10.1.3 Hazard communication

The label elements for acute toxic substances and mixtures are given in table 24. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 24 — Acute toxicity label elements**

1	2	3	4	5	6
	<b>Category 1</b>	<b>Category 2</b>	<b>Category 3</b>	<b>Category 4</b>	<b>Category 5</b>
<b>Symbol</b>	Skull and crossbones	Skull and crossbones	Skull and crossbones	Exclamation mark	No symbol is used
<b>Signal word</b>	Danger	Danger	Danger	Warning	Warning
<b><u>Hazard statement</u></b>					
<b>Oral</b>	Fatal if swallowed	Fatal if swallowed	Toxic if swallowed	Harmful if swallowed	May be harmful if swallowed
<b>Dermal</b>	Fatal in contact with skin	Fatal in contact with skin	Toxic in contact with skin	Harmful in contact with skin	May be harmful in contact with skin
<b>Inhalation<sup>a</sup></b>	Fatal if inhaled	Fatal if inhaled	Toxic if inhaled	Harmful if inhaled	May be harmful if inhaled

<sup>a</sup> If a substance or a mixture is also corrosive (based on skin or eye data), the corrosivity hazard may be communicated as a symbol or hazard statement. That is, in addition to an appropriate acute toxicity symbol, the corrosive symbol as used for skin and eye corrosivity may be added along with a corrosivity hazard statement such as "corrosive" or "corrosive to the respiratory tract."

## 10.2 Skin corrosion and skin irritation

### 10.2.1 Classification criteria for substances

#### 10.2.1.1 General

**10.2.1.1.1** Several factors shall be taken into account in determining the skin corrosion (see 3.1.77) potential or the skin irritation (see 3.1.78) potential of a chemical before testing is undertaken. For example, solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. Existing human experience and data, including single or repeated exposure (or both) and animal observations and data shall be taken into account, as they give information directly relevant to effects on the skin. Information from structurally related compounds can be used to make classification decisions. Likewise, a pH value equal to or less than 2 or a pH value equal to or more than 11,5 can indicate skin effects, especially when buffering capacity is known. Although the correlation is not perfect, such chemicals are expected to produce significant effects on the skin and shall be classified as corrosive, also when the buffering capacity is unknown. The acid/alkali reserve could also be taken into account if there are indications that the substance is not corrosive despite a low or a high pH value. In such a case, further *in vitro* testing needs to be done.

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**10.2.1.1.2** When skin corrosion or skin irritation is observed in acute toxicity studies (see flow chart 2), additional testing need not be done, provided that the dilutions used and the species tested are equivalent. *In vitro* alternatives that have been validated and accepted can also be used to help make classification decisions.

Step	Parameter	Finding	Conclusion
1a	Existing human or animal experience <sup>g</sup>	→ Corrosive	→ Classify as corrosive <sup>a</sup>
	↓ Not corrosive or no data		
1b	Existing human or animal experience <sup>g</sup>	→ Irritant	→ Classify as irritant <sup>a</sup>
	↓ Not irritant or no data		
1c	Existing human or animal experience	→ Not corrosive or irritant	→ No further testing, not classified
	↓ No data		
2a	Structure-activity relationships or structure-property relationships <sup>b</sup>	→ Corrosive	→ Classify as corrosive <sup>a</sup>
	↓ Not corrosive or no data		
2b	Structure-activity relationships or structure-property relationships <sup>b</sup>	→ Irritant	→ Classify as irritant <sup>a</sup>
	↓ Not irritating or no data		
3	pH with buffering <sup>c</sup>	→ pH ≤ 2 or pH ≥ 11,5	→ Classify as corrosive <sup>a</sup>
	↓ Not pH extreme or no data		
4	Existing skin data in animals indicate no need for animal testing <sup>d</sup>	→ Yes	→ Possibly no further testing may be deemed corrosive/ irritant
	↓ No indication or no data		
5	Valid and accepted <i>in vitro</i> skin corrosion test <sup>e</sup>	→ Positive response	→ Classify as corrosive <sup>a</sup>
	↓ Negative response or no data		

**Flow chart 2 — Tiered approach to the evaluation of skin corrosion and skin irritation potential**

**Flow chart 2 (concluded)**

Step	Parameter	Finding	Conclusion
<b>6</b>	Valid and accepted <i>in vitro</i> skin irritation test <sup>f</sup>	Positive response	Classify as irritant <sup>a</sup>
	Negative response or no data		
<b>7</b>	<i>In vivo</i> skin corrosion test (one animal)	Corrosive response	Classify as corrosive <sup>a</sup>
	Negative response		
<b>8</b>	<i>In vivo</i> skin irritation test (three animals total) <sup>h</sup>	Positive response	Classify as irritant <sup>a</sup>
	Negative response	No further testing	No further testing, not classified
<b>9</b>	When it is ethical to perform human patch testing <sup>g</sup>	Irritant response	Classify as irritant <sup>a</sup>
	Not as above	Non-irritant response	No further testing, not classified

<sup>a</sup> Classify in the appropriate subcategory (see 10.2.1.2.2).

<sup>b</sup> Structure-activity and structure-property relationships are presented separately but should be conducted in parallel.

<sup>c</sup> Measurement of pH alone might be adequate, but assessment of the acid or the alkali reserve is preferable. Methods are needed to assess the buffering capacity.

<sup>d</sup> Existing animal data should be carefully reviewed to determine if *in vivo* skin corrosion testing or *in vitro* skin irritation testing is needed. For example, testing might not be needed when no skin irritation was produced in an acute skin toxicity test at the limit dose, or when very toxic effects were produced in an acute skin toxicity test. In the latter case, the substance should be classified as being very hazardous by the dermal route for acute toxicity; it is moot whether the material is also irritating or corrosive on the skin. When evaluating acute skin toxicity information, it should be kept in mind that the reporting of skin lesions could be incomplete, testing and observations could have been made on a species other than the rabbit, and that species might differ in sensitivity in their responses.

<sup>e</sup> Internationally accepted validated *in vitro* test methods for skin corrosion are OECD Test Guidelines 430 and 431 (see annex J).

<sup>f</sup> At present there are no validated and internationally accepted *in vitro* test methods for skin irritation testing.

<sup>g</sup> This evidence could be derived from single or repeated exposures. At present there are no validated and internationally accepted test methods for human skin irritation testing.

<sup>h</sup> Testing is usually conducted on three test animals. One of these test animals should have been used in a test where negative corrosion results were obtained.

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**10.2.1.1.3** All the information that is available on a chemical shall be used in determining the need for *in vivo* skin irritation testing. Although information might be gained from the evaluation of single parameters within a tier (see 10.2.1.1.4), for example, caustic alkalis with a pH value of 11,5 or greater can be considered as skin corrosives, there is merit in considering the totality of existing information and making an overall weight of evidence determination. This is especially true when information is available on some, but not all, parameters. Generally, case-by-case studies of existing human experience and data should be taken into account, followed by animal experience and testing data, and lastly other sources of information.

**10.2.1.1.4** A tiered approach to the evaluation of initial information should be followed, where applicable, recognizing that all elements might not be relevant in certain cases. Flow chart 2 outlines the process to be followed for the classification of chemicals for skin corrosion and skin irritation.

### **10.2.1.2 Skin corrosion**

**10.2.1.2.1** A substance corrosive to the skin is classified in a single category (see 10.2.1.2.2), based on animal testing. Corrosive reactions are typified by ulcers, bleeding, bloody scabs and, by the end of a 14 d observation period, by discoloration due to blanching of the skin, complete areas of alopecia and scars. Histopathology should be considered to discern questionable lesions.

**10.2.1.2.2** Three subcategories are provided within the single corrosive category:

- a) **subcategory 1A** – where responses are noted after an exposure of up to 3 min and an observation time of up to 1 h;
- b) **subcategory 1B** – where responses are noted after an exposure of between 3 min and 1 h and an observation period of up to 14 d; and
- c) **subcategory 1C** – where responses occur after an exposure of between 1 h and 4 h and an observation period of up to 14 d.

### **10.2.1.3 Skin irritation**

**10.2.1.3.1** Reversibility of skin lesions should be taken into account in the evaluation of skin irritant responses. A substance should be considered a skin irritant when inflammation persists to the end of the observation period in 2 or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling.

**10.2.1.3.2** Skin irritant responses in animal testing can be quite variable, as they are with skin corrosion. A substance can be regarded as a skin irritant if at least 1 of 3 test animals shows a very elevated mean score throughout the study, including persistent skin lesions at the end of an observation period of normally, 14 d. Although other responses could also fulfil this criterion, it should, however, be ascertained that the responses are the result of chemical exposure.

**10.2.1.3.3** A skin irritant is classified in one of the two categories as indicated in table 25.



**Table 25 — Categories and classification criteria for skin irritants**

1	2
Categories	Classification criteria
2	<p>a) A mean value equal to or more than 2,3 and less than 4,0 for erythema/eschar or for oedema in at least two of the three test animals from gradings at 24 h, 48 h and 72 h after patch removal, or</p> <p>b) inflammation that persists to the end of the observation period, normally 14 d, in at least two of the three test animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia and scaling; or</p> <p>c) in some cases where there is pronounced variability of response among test animals, with very definite positive effects related to chemical exposure in one test animal, but less than the criteria given in a) and b) above.</p>
3	<p>a) A mean value equal to or more than 1,5 and less than 2,3 for erythema/eschar or for oedema in at least two of the three test animals from gradings at 24 h, 48 h and 72 h after patch removal; or</p> <p>b) if reactions are delayed, from grades on three consecutive days after onset of the skin reactions and when not included in category 2.</p>

## 10.2.2 Classification criteria for mixtures

### 10.2.2.1 Classification of mixtures when data are available for the complete mixture

**10.2.2.1.1** A mixture shall be classified by using the criteria for the substances contained therein and taking into account the testing and evaluation strategies to develop data for skin corrosion and skin irritation.

**10.2.2.1.2** Unlike other hazard classes, alternative tests are available for skin corrosion of certain types of chemicals. These tests give accurate results for classification purposes, as well as being simple and relatively inexpensive to perform. The tiered weight of evidence strategy (see flow chart 2) can be used to ensure an accurate classification, as well as to avoid unnecessary animal testing.

**10.2.2.1.3** A mixture is considered a category 1 skin corrosive if it has a pH  $\leq 2$  or a pH  $\geq 11,5$ . If the alkali or acid reserve of a mixture suggests that the mixture might not be corrosive to the skin despite the low or high pH value, further testing needs to be carried out by means of an appropriate validated *in vitro* test to confirm this.

### 10.2.2.2 Classification of mixtures when data are not available for the complete mixture: Bridging principles

#### 10.2.2.2.1 General

Where the mixture itself has not been tested to determine its skin corrosion properties or its skin irritation properties, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the bridging principles as given in 10.2.2.2.2 to 10.2.2.2.7. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional animal testing.

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### **10.2.2.2.2 Dilution**

If a mixture is diluted with a substance that has an equivalent, or lower, corrosive or irritant classification than the least corrosive or irritant original ingredient and which is not expected to affect the corrosive or irritant properties of other ingredients, then the new mixture can be classified as equivalent to the original mixture. Alternatively, the method explained in 10.2.2.3 can be applied.

### **10.2.2.2.3 Batching**

The corrosion or irritation potential of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by, or under, the control of the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the batch has changed. If the latter occurs, a new classification is necessary.

### **10.2.2.2.4 Concentration of mixtures of the highest corrosion category and the highest irritation category**

**10.2.2.2.4.1** If a tested mixture classified in the highest subcategory for corrosion (see 10.2.1.2.2) is concentrated, a more concentrated mixture shall remain classified in the highest corrosion subcategory without additional testing.

**10.2.2.2.4.2** If a tested mixture classified in the highest category for skin irritation is concentrated and does not contain corrosive ingredients, a more concentrated mixture shall be classified in the highest irritation category without additional testing.

### **10.2.2.2.5 Interpolation within one category**

For three mixtures, with identical ingredients, where mixture A and mixture B are in the same corrosive or irritant category, and mixture C has the toxicologically active ingredients with concentrations intermediate to the concentrations of those ingredients in mixtures A and B, then mixture C is assumed to be in the same irritation or corrosion category as mixture A and mixture B.

### **10.2.2.2.6 Substantially similar mixtures**

In the case of two mixtures (A+B) and (C+B) where:

- a) the concentration of ingredient B is essentially the same in both mixtures;
- b) the concentration of ingredient A equals that of ingredient C;
- c) the toxicity data for ingredient A and ingredient C are available and substantially equivalent, that is, they are in the same hazard category and are not expected to affect the toxicity of B; and
- d) mixture (A+B) has already been classified based on test data,

then mixture (C+B) can be assigned the same hazard category as that of mixture (A+B).

### **10.2.2.2.7 Aerosols**

A mixture in aerosol form can be classified in the same hazard category as the tested non-aerosol form, provided that the added propellant does not affect the irritation or corrosive properties of the mixture upon spraying.

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### 10.2.2.3 Classification of mixtures when data are available for all components or only for some components of the mixture

**10.2.2.3.1** In order to make use of all available data for purposes of classifying a mixture for skin corrosion or skin irritation, the tiered approach (see flow chart 2) shall be followed where appropriate.

The ingredients of a mixture relevant for classification purposes are those ingredients present in concentrations of 1 % (by mass for solids, liquids, dusts, mists and vapours and by volume for gases) or greater. However, an ingredient present at a concentration of less than 1 % can still be relevant for classification of the mixture as corrosive or irritating to the skin (see 10.2.2.3.3).

**10.2.2.3.2** When skin corrosion or skin irritation data are available for the components of a mixture, but not for the mixture as a whole, classification of the mixture shall be based on the theory of additivity. This is when each corrosive or irritant component contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive components when they are present at a concentration below the concentration limit for classification in category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as corrosive or irritant when the sum of the concentrations of such components exceeds a cut-off concentration limit (see table 26).

**Table 26 — Cut-off values/concentration limits of the ingredients of a mixture classified as skin category 1, 2 or 3 that trigger classification of the mixture as hazardous to skin (category 1, 2 or 3)**

1	2	3	4
Sum of ingredients classified as:	Cut-off values/concentration limits of the ingredients that trigger classification of a mixture		
	% (by mass for solids, liquids dusts mists and vapours and by volume for gases)		
	Skin corrosive	Skin irritant	
	Category 1	Category 2	Category 3
Skin category 1	≥ 5	≥ 1 but < 5	
Skin category 2		≥ 10	10 > C ≥ 1
Skin category 3			≥ 10
(10 x skin category 1) + skin category 2		≥ 10	10 > C ≥ 1
(10 x skin category 1) + skin category 2 + skin category 3			≥ 10

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**10.2.2.3.3** Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes and phenols. The classification procedures given in 10.2.2.3.1 and 10.2.2.3.2 are not applicable to these types of substances as they are often corrosive or irritant at concentrations of less than 1 %. The pH value shall be used for the classification of mixtures containing strong acids or strong bases (see 10.2.2.1.3), since the pH-value is a better indicator of corrosion than the concentration limits given in table 26. A mixture that contains corrosive or irritant components and that cannot be classified in accordance with the additivity approach (see table 26) because of chemical characteristics, shall be classified as indicated in table 27.

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**10.2.2.3.4** A mixture shall be classified as corrosive or irritant, as appropriate, when data show that (an) ingredient(s) of the mixture is corrosive or irritant at a concentration of less than 1 % for corrosives and less than 3 % for irritants (see also 5.5).

**Table 27 — Cut-off values/concentration limits of the ingredients of a mixture for which the additivity approach does not apply, that trigger classification of the mixture as hazardous to skin**

1	2	3
Properties of the ingredient	Cut-off values/concentration limits that trigger classification of the mixture %	Classification of mixture as hazardous to skin
Acid with $\text{pH} \leq 2$	$\geq 1$	Category 1
Alkali with $\text{pH} \geq 11,5$	$\geq 1$	Category 1
Other corrosive (category 1) ingredients for which additivity does not apply	$\geq 1$	Category 1
Other irritant (category 2) ingredients for which additivity does not apply, including acids and bases	$\geq 3$	Category 2

**10.2.2.3.5** On occasion, reliable data might show that the skin corrosion or the skin irritation properties of an ingredient are not evident, although the ingredient is present at a level above the generic concentration cut-off levels indicated in table 26 and table 27. In such a case the mixture can be classified according to those data (see also 5.6). When it is expected that the skin corrosion or skin irritation properties of an ingredient will not be evident when present at a level above the generic concentration cut-off levels mentioned in table 26 and table 27, testing of the mixture need to be considered. In such a case, the tiered approach shall be applied as described in 10.2.1.1.4 and flow chart 2.

### 10.2.2.4 Hazard communication

The label elements for substances and mixtures that are skin corrosives or skin irritants are given in table 28. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 28 — Label elements for skin corrosion/irritation**

1	2	3	4	5	6
	<b>Category 1</b>			<b>Category 2</b>	<b>Category 3</b>
	<b>1 A</b>	<b>1 B</b>	<b>1 C</b>		
<b>Symbol</b>	Corrosion	Corrosion	Corrosion	Exclamation mark	No symbol is used
<b>Signal word</b>	Danger	Danger	Danger	Warning	Warning
<b>Hazard statement</b>	Causes severe skin burns and eye damage	Causes severe skin burns and eye damage	Causes severe skin burns and eye damage	Causes skin irritation	Causes mild skin irritation

## 10.3 Serious eye damage and eye irritation

### 10.3.1 Classification criteria for substances

**10.3.1.1** In order to avoid unnecessary animal testing, the classification of substances and mixtures for serious eye damage (see 3.1.75) and eye irritation (see 3.1.37) is based on a tiered testing and evaluation scheme that combines pre-existing information on serious eye damage and eye irritation. Such data relate to historical human or animal experience, considerations on SAR or SPR, and the results obtained from validated *in vitro* tests (see annex J).

**10.3.1.2** All existing information on a substance shall be reviewed before any *in vivo* testing for serious eye damage or eye irritation is undertaken. Preliminary decisions can often be made from existing data as to whether a substance causes serious (irreversible) damage to the eyes. If a substance can be classified on this information, no testing is required. Alternatively, the tiered approach (see flow chart 3) can be used for the evaluation of existing information on substances or the evaluation of new uninvestigated substances.

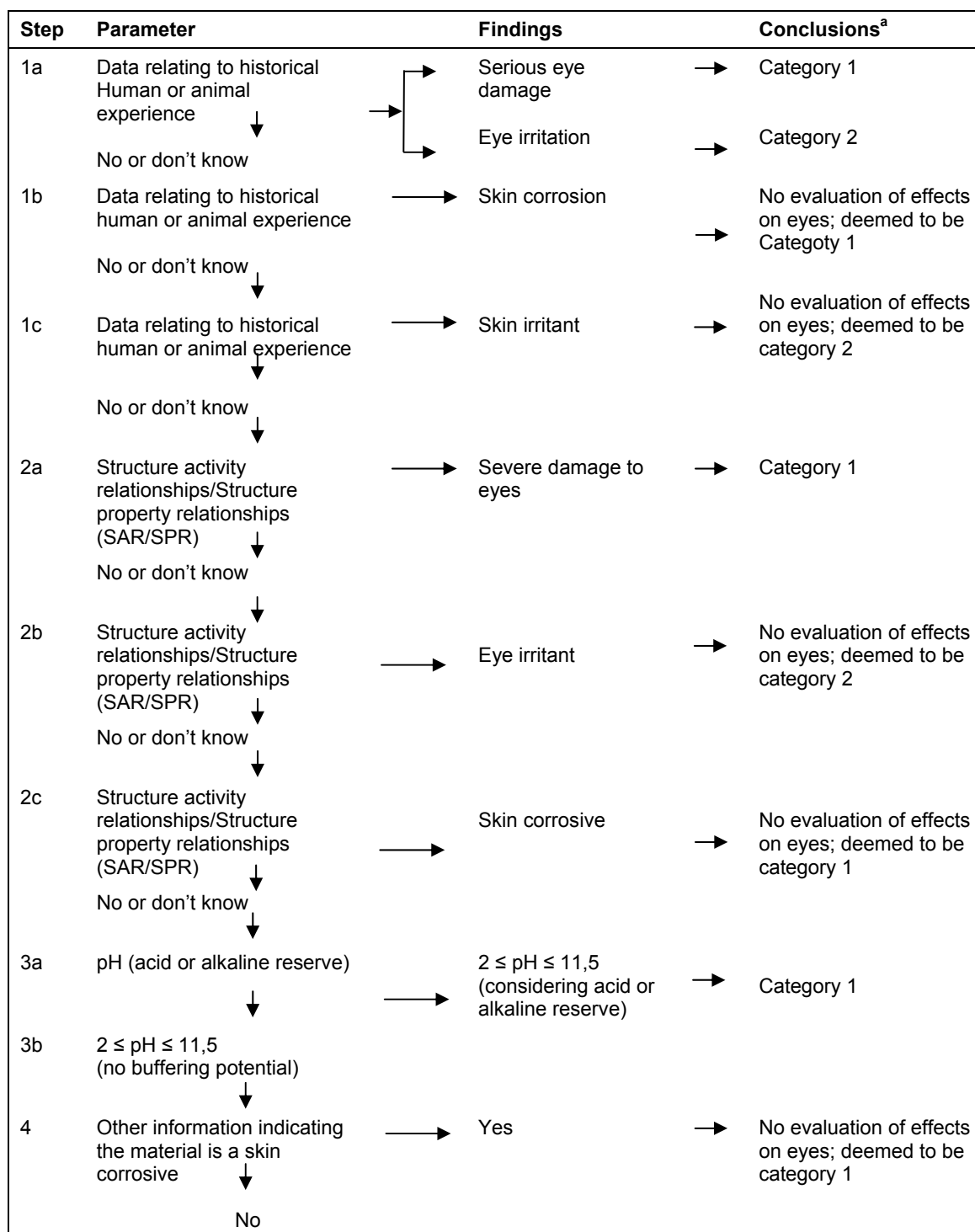
**10.3.1.3** Several factors on the serious eye damage potential or the eye irritation potential of a substance should be considered before testing is undertaken. Firstly, existing human and animal experience should be taken into account as it gives information directly relevant to effects on the eye. In some cases information from structurally related compounds might be available that could be used for the evaluation of serious eye damage or eye irritation potential. Likewise, a substance with a pH  $\leq 2$  or a pH  $\geq 11,5$  can produce serious eye damage, especially when associated with significant buffering capacity. Possible skin corrosion has to be evaluated prior to consideration of serious eye damage or eye irritation in order to avoid testing for local effects on eyes with skin corrosive substances. *In vitro* alternatives that have been validated and accepted may be used to make classification decisions.

**10.3.1.4** All the information that is available on a chemical shall be used in determining the need for *in vivo* eye irritation testing. Although information might be gained from the evaluation of single parameters within a tier (see 10.3.1.5 and flow chart 3), for example an alkali with a pH  $\geq 11,5$  can be considered as a local corrosive, there is merit in considering the totality of existing information and making an overall weight of evidence determination. Generally, primary emphasis should be placed upon expert judgement, taking into account human experience with the substance, followed by the outcome of skin irritation testing and of well validated alternative methods. Animal testing with corrosive substances should be avoided whenever possible.

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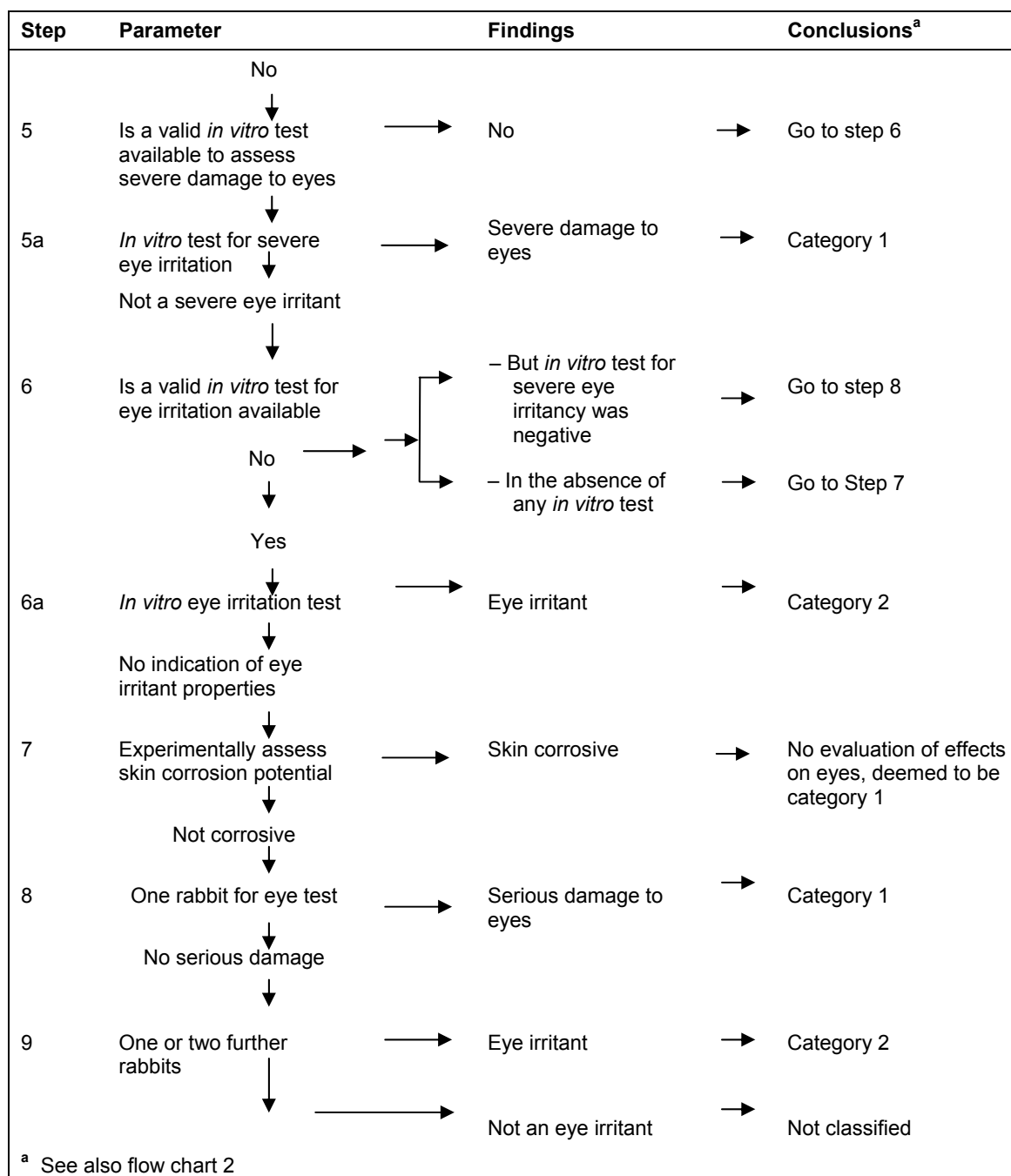
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**10.3.1.5** A tiered approach to the evaluation of initial information should be followed where applicable, recognizing that all elements might not be relevant in certain cases. Flow chart 3 outlines the process to be followed for the classification of chemicals for serious eye damage and eye irritation.



**Flow chart 3 — Tiered approach to classification for serious eye damage and eye irritation**

**Flow chart 3 (concluded)**



#### 10.3.1.6 Implementation of flow chart 3

##### Steps 1a and 1b

Pre-existing information on eye irritation and skin corrosion is shown separately because evaluation of skin corrosion has to be considered if no information on local effects on eyes is available. Analysis of pre-existing experience with the chemical might identify serious eye damage, corrosion and irritation potential for both skin and eye effects:

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- a) **step 1a** – reliable determination of eye irritation based on human or animal experience depends on expert judgement. In most cases human experience is based on accidental events and thus the local effects detected after an accident have to be compared with classification criteria created for evaluation of animal test data;
- b) **step 1b** – substances corrosive to the skin, shall not be instilled into the eyes of test animals as this will lead to serious damage to the eyes as well (category 1).

**Steps 2a and 2b** The SAR/SPR for eye irritation and skin corrosion are shown separately but in reality would be done in parallel. Step 2a and step 2b shall be completed by using validated and accepted SAR/SPR approaches to identify serious eye damage, corrosion and irritation potential for both skin and eyes:

- a) **step 2a** – reliable determination of eye irritation is based only on theoretical evaluations. In most cases it will only be appropriate for substances that are homologous to chemicals with very well known properties;
- b) **step 2b** – if the theoretical evaluation indicates that a substance is corrosive to the skin, it shall not be instilled into the eyes of test animals as this will lead to serious damage to the eyes as well (category 1).

**Step 3** A  $\text{pH} \leq 2$  or a  $\text{pH} \leq 11,5$  generally indicates strong local effects, especially in combination with assessment of acid or alkaline reserve. Such physico-chemical properties can be taken as leading to serious damage to the eyes (category 1).

**Step 4** All attainable information need be taken into account, including human experience. However, the information shall be restricted to existing data, for example, the results of an acute dermal toxicity ( $LD_{50}$ ) test on skin corrosion.

**Step 5** *In vitro* tests shall be used as alternative methods to validated internationally agreed principles and criteria (see 5.1) for the assessment of eye irritation or serious damage to eyes, such as irreversible corneal opacity.

**Step 6** This step seems not to be achievable in the near future. Validated alternative methods for the reliable assessment of (reversible) eye irritation need to be developed.

**Step 7** In the absence of any other relevant information, it is essential to obtain information by means of an internationally recognized corrosion or irritation test (see annex J), before proceeding to a rabbit eye irritation test. This can be achieved in a staged manner by firstly using a validated, accepted *in vitro* skin corrosivity assay. If this is not available, then the assessment shall be completed by means of animal tests (see 10.2.1).

**Step 8** A staged approach shall be followed for eye irritation *in vivo*. No further testing is needed if serious eye damage is detected in a limit test with one test rabbit.

**Step 9** Where two test animals give clearly irritant or clearly non-irritant responses, no further testing is needed. However, in the case of different, or borderline responses, a third test animal needs to be used. The result of this three-animal test is sufficient to indicate whether classification is required or not.



### **10.3.1.7 Irreversible effects on the eye or serious damage to eyes (category 1)**

**10.3.1.7.1** A substance shall be classified in category 1 if it has the potential to induce serious irreversible damage to the eyes. The classification criteria are as follows:

- a) effects on the cornea, iris or conjunctiva in at least one test animal that are not expected to reverse or have not fully reversed within an observation period of 21 d;
- b) a positive response of corneal opacity  $\geq 3$  or iritis  $\geq 1,5$  (or both) on exposure to the test material for a period of 24 h, 48 h and 72 h, as applicable.

**10.3.1.7.2** The observations include test animals with grade 4 cornea lesions and other severe reactions, for example destruction of the cornea observed at any time during the test, persistent corneal opacity, discoloration of the cornea by a dye substance, adhesion, pannus, and interference with the function of the iris, or other effects that impair sight. In this context, persistent lesions are considered as those that are not fully reversible within an observation period of 21 d.

### **10.3.1.8 Reversible effects on the eye (category 2)**

A substance is classified in category 2 if it has the potential to induce reversible eye irritation. The category provides the option to classify substances in two subcategories, viz. irritating to eyes and mildly irritating to eyes (see table 29).

**Table 29 — Subcategories and classification criteria for reversible eye effects**

1	2
Subcategory	Classification criteria
2A	A positive response in at least 2 or 3 test animals on exposure to the test material for a period of 24 h, 48 h and 72 h, but which fully reverses within an observation period of 21 d: <ul style="list-style-type: none"> <li>a) corneal opacity <math>\geq 1</math>, and/or</li> <li>b) iritis <math>\geq 1</math>, and/or</li> <li>c) conjunctival redness <math>\geq 2</math>, and/or</li> <li>d) conjunctival oedema (chemosis) <math>\geq 2</math>;</li> </ul>
2B	The effects given for category 2A are fully reversible within an observation period of 7 d.

## **10.3.2 Classification criteria for mixtures**

### **10.3.2.1 Classification of mixtures when data are available for the complete mixture**

**10.3.2.1.1** A mixture shall be classified by using the criteria for the substances contained therein, and taking into account the testing and evaluation strategies used to develop data for these hazard classes.

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**10.3.2.1.2** Unlike other hazard classes, alternative tests are available for skin corrosion of certain types of chemicals. These tests give accurate results for classification purposes, as well as being simple and relatively inexpensive to perform. The tiered approach (see flow chart 3) can be used for skin corrosion and serious eye damage and eye irritation to ensure an accurate classification, as well as to avoid unnecessary animal testing.

**10.3.2.1.3** A mixture is considered to cause serious eye damage (category 1) if it has a  $\text{pH} \leq 2$  or a  $\text{pH} \geq 11,5$ . If the alkali or acid reserve suggests that the mixture might not have the potential to cause serious eye damage despite the low or high pH value, further testing needs to be carried out by means of an appropriate validated *in vitro* test (see annex J).

### **10.3.2.2 Classification of mixtures when data are not available for the complete mixture: Bridging principles**

#### **10.3.2.2.1 General**

Where the mixture itself has not been tested to determine its skin corrosive properties or its potential to cause serious eye damage or irritation, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterise the hazards of the mixture, these data shall be used in accordance with the bridging principles as given in 10.3.2.2.2 to 10.3.2.2.7. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional animal testing.

#### **10.3.2.2.2 Dilution**

If a mixture is diluted with a substance that has an equivalent, or lower, classification for serious eye damage or eye irritation than the least damaging or irritant original ingredient and that is not expected to affect the corrosive or irritant properties of other ingredients, then the new mixture can be classified as equivalent to the original mixture. Alternatively, the method given in 10.3.2.3 can be applied.

#### **10.3.2.2.3 Batching**

The irritation or serious eye damage potential of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by, or under, the control of the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the batch has changed. If the latter occurs, a new classification is necessary.

#### **10.3.2.2.4 Concentration of mixtures of the highest serious eye damage category and the highest eye irritation category**

**10.3.2.2.4.1** If a tested mixture, classified in category 1 for serious eye damage, is concentrated, a more concentrated mixture shall remain classified in category 1 without additional testing.

**10.3.2.2.4.2** If a tested mixture, classified in the highest subcategory for skin or eye irritation, is concentrated and does not contain ingredients that cause serious eye damage, a more concentrated mixture shall remain classified in the highest subcategory for skin or eye irritation without additional testing.

#### **10.3.2.2.5 Interpolation within one toxicity category**

For three mixtures with identical ingredients, where mixture A and mixture B are in the same irritation or serious eye damage toxicity category, and mixture C has the same toxicologically active ingredients with concentrations intermediate to the concentrations of those ingredients in mixtures A and B, then mixture C is assumed to be in the same eye irritation or serious eye damage category as mixture A and mixture B.

#### **10.3.2.2.6 Substantially similar mixtures**

In the case of two mixtures (A + B) and (C + B) where

- a) the concentration of ingredient B is essentially the same in both mixtures,
- b) the concentration of ingredient A equals that of ingredient C,
- c) the irritation or serious eye damage data, as applicable, for ingredient A and ingredient C are available and substantially equivalent, and
- d) mixture (A + B) has been classified by testing,

then mixture (C + B) can be assigned the same hazard category as that of mixture (A + B).

#### **10.3.2.2.7 Aerosols**

A mixture in the form of an aerosol can be classified in the same hazard category as the non-aerosol form, provided that the added propellant does not affect the irritation or corrosive properties of the mixture upon spraying.

#### **10.3.2.3 Classification of mixtures when data are available for all components or only for some components**

**10.3.2.3.1** In order to make use of all available data for purposes of classifying a mixture for eye irritation or serious eye damage properties, the tiered approach (see flow chart 3) shall be followed.

**10.3.2.3.2** The ingredients of a mixture relevant for classification are those ingredients which are present in concentrations of 1 % (by mass for solids, liquids, dusts, mists and vapours, and by volume for gases) or greater. However, an ingredient present at a concentration of less than 1 %, for example a corrosive ingredient, can still be relevant for the classification of a mixture for eye irritation or serious eye damage.

**10.3.2.3.3** When data are available on the components, but not on the mixture as a whole, classification of a mixture as an eye irritant or as seriously damaging to the eye is based on the theory of additivity where each corrosive or irritant component contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration.

A weighting factor of 10 is used for corrosive components when they are present at a concentration below the concentration limit for classification in category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. A mixture is classified as seriously damaging to the eye or as a severe eye irritant when the sum of the concentrations of such components exceeds a threshold cut-off concentration limit (see table 30).

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**Table 30 — Cut-off values/concentration limits of the ingredients of a mixture classified as category 1 for skin effects and/or category 1 or 2 for eye effects that trigger classification of the mixture as hazardous to the eye**

1	2	3
Sum of ingredients classified as:	Cut-off values/concentration limits of the ingredients that trigger classification of a mixture	
	%	
	Irreversible eye effects	Reversible eye effects
	Category 1	Category 2
Eye or skin category 1	$\geq 3$	$3 > C \geq 1$
Eye category 2A		$\geq 10$
(10 x eye category 1) + eye category 2A		$\geq 10$
Skin category 1 + eye category 1	$\geq 3$	$3 > C \geq 1$
10 x (Skin category 1 + eye category 1) + eye category 2A or 2B		$\geq 10$

**10.3.2.3.4** Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes and phenols. The approach explained in 10.3.2.3.1 to 10.3.2.3.3 might not work given that many of such substances are corrosive or irritant at concentrations lower than 1 %. For mixtures containing strong acids or bases, the pH value shall be used as classification criteria (see 10.3.2.1.3) since pH is a better indicator of serious eye damage than the concentration limits given in table 30. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach applied in table 30 due to chemical characteristics that make this approach unworkable, shall be classified as follows:

- a) eye category 1 if it contains  $\geq 1$  % of a corrosive ingredient; and
- b) eye category 2 when it contains  $\geq 3$  % of an irritant ingredient.

Classification of mixtures with ingredients for which the approach in table 30 does not apply is summarised in table 31.

**Table 31 — Cut-off values/concentration limits of the ingredients of a mixture for which the additivity approach does not apply, that trigger classification of the mixture as hazardous to the eye**

1	2	3
Ingredient	Cut-off values/concentration limits of ingredients that trigger classification of a mixture %	Classification of a mixture as hazardous to the eye
Acid with pH ≤ 2	≥ 1	Category 1
Alkali with pH ≥ 11,5	≥ 1	Category 1
Other corrosive (category 1) ingredients for which additivity does not apply	≥ 1	Category 1
Other irritant (category 2) ingredients for which additivity does not apply, including acids and bases	≥ 3	Category 2

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**10.3.2.3.5** On occasion, reliable data might show that the reversible/irreversible eye effects of an ingredient would not be evident when present at a level above the generic cut-off values/concentration limits given in table 30 and table 31. In these cases the mixture can be classified according to those data (see also 5.6). On occasion, when it is expected that the skin corrosion/irritation or the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic cut-off concentration limits given in table 30 and table 31, testing of the mixture needs to be considered. In these cases, the tiered approach shall be applied as given in 10.3.1 and flow chart 3.

**10.3.2.3.6** If data show that an ingredient(s) is corrosive or irritant at a concentration less than 1 % (corrosive) or less than 3 % (irritant), the mixture shall be classified accordingly (see also 5.6).

### 10.3.3 Hazard communication

The label elements for substances and mixtures that cause serious eye damage and eye irritation are given in table 32. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*;
- c) annex B, *Hazard communication and classification summary*.

**Table 32 — Label elements for serious eye damage/eye irritation**

1	2	3	4
	Category 1	Category 2A	Category 2B
<b>Symbol</b>	Corrosive	Exclamation mark	No symbol is used
<b>Signal word</b>	Danger	Warning	Warning
<b>Hazard statement</b>	Causes severe eye damage	Causes severe eye irritation	Causes eye irritation

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### **10.4 Respiratory sensitization and skin sensitization**

#### **10.4.1 Classification criteria for substances causing respiratory sensitization**

##### **10.4.1.1 Hazard category**

A substance shall be classified as a respiratory sensitizer (see 3.1.71) of category 1 when human evidence shows that the substance can induce specific respiratory hypersensitivity, or when positive results from animal tests are available.

##### **10.4.1.2 Human evidence**

**10.4.1.2.1** Evidence that a substance can induce specific respiratory hypersensitivity is normally based on human experience. In this context asthma, and also rhinitis (conjunctivitis) and alveolitis are considered as respiratory hypersensitivity. The condition has the clinical character of an allergic reaction but immunological mechanisms do not have to be demonstrated.

**10.4.1.2.2** When considering the human evidence, it is necessary for a decision on classification to take into account the size of the population exposed and the extent of exposure, in addition to evidence from the cases mentioned in 10.4.1.2.3.

**10.4.1.2.3** The evidence referred to in 10.4.1.2.2 can be:

- a) a clinical history and data from appropriate lung function tests related to exposure to the substance and confirmed by other supportive evidence such as
  - 1) an *in vivo* immunological test, for example skin prick test,
  - 2) an *in vitro* immunological test, for example serological analysis,
  - 3) studies that indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, for example repeated low-level irritation, pharmacologically mediated effects,
  - 4) a chemical structure related to substances known to cause respiratory hypersensitivity, and
- b) data from positive bronchial challenge tests with the substance conducted in accordance with accepted guidelines for the determination of a specific hypersensitivity reaction.

**10.4.1.2.4** The clinical history shall include both the medical and the occupational history in order to determine a relationship between exposure to a specific substance and the development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, the family history and the medical history of the patient in question. The medical history shall also include a note of other allergic disorders or airway disorders from childhood, and the smoking history.

**10.4.1.2.5** The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is however, recognised that in practice many of the examinations listed above will already have been carried out.

#### **10.4.1.3 Animal studies**

Data from animal studies that indicate the potential of a substance to cause sensitization by inhalation in humans include:

- a) measurements of immunoglobulin E (*IgE*) and other specific immunological parameters, for example in mice; and
- b) specific pulmonary responses in guinea pigs.

NOTE 1 At present recognised animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances animal testing can be used, for example, a modification of the guinea pig maximization test for the determination of relative allergenicity of proteins. However, these tests still need further validation.

NOTE 2 The mechanisms by which substances induce symptoms of asthma are not yet fully known. For preventative measures, these substances are considered respiratory sensitizers. However, if, on the basis of the evidence it can be demonstrated that these substances induce symptoms of asthma by irritation only in people with bronchial hyperreactivity, they should not be considered as respiratory sensitizers.

#### **10.4.2 Classification criteria for substances causing skin sensitization**

##### **10.4.2.1 Hazard category**

A substance shall be classified as a skin sensitizer (see 3.1.79) of category 1 when there is evidence in humans that the substance can induce sensitization by skin contact in a substantial number of persons, or when positive results from animal tests are available.

##### **10.4.2.2 Specific considerations for the classification of skin sensitizers**

**10.4.2.2.1** For the classification of a substance as a skin sensitizer any, or all, of the following shall apply:

- a) positive data from patch testing, normally obtained in more than one dermatology clinic;
- b) epidemiological studies showing allergic contact dermatitis caused by the substance;
- c) situations where a high proportion of those exposed to the substance exhibit characteristic symptoms that are to be looked at with special concern, even if the number of cases is small;
- d) positive data from appropriate animal studies;
- e) positive data from studies in humans (see 5.3); and
- f) well documented episodes of allergic contact dermatitis, normally obtained in more than one dermatology clinic.

**10.4.2.2.2** Positive effects in either humans or animals justify classification. Evidence from animal studies is usually more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources shall be assessed in order to resolve the question of classification on a case-by-case basis. Normally, human data are not generated in controlled experiments with volunteers for the purpose of hazard classification but rather as part of risk assessment to confirm lack of effects seen in animal tests. Consequently, positive human data on contact sensitization are usually derived from case-control or other less defined studies. Evaluation of human data shall therefore be carried out with caution as the frequency of cases reflect, in addition to the inherent properties of the substance, factors such as the exposure situation,

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bioavailability, individual predisposition and preventive measures taken. Negative human data shall not be used to negate positive results from animal studies.

**10.4.2.2.3** If none of the conditions mentioned in 10.4.2.2.1 and 10.4.2.2.2 are met, the substance needs not be classified as a skin sensitizer. However, a combination of two or more indicators of skin sensitization as listed below can alter the decision and shall be considered on a case-by-case basis:

- a) isolated episodes of allergic contact dermatitis;
- b) epidemiological studies of limited power, for example where chance, bias or confounders have not been ruled out fully with reasonable confidence;
- c) data from animal tests performed in accordance with existing guidelines and which do not meet the criteria for a positive result given in 10.4.2.4.1, but which are sufficiently close to the limit to be considered significant;
- d) positive data from non-standard methods; and
- e) positive results from close structural analogues.

#### **10.4.2.3 Immunological contact urticaria (nettle-rash)**

**10.4.2.3.1** A substance that meets the classification criteria for a respiratory sensitizer can, in addition, cause immunological contact urticaria (nettle-rash). Such a substance can also be classified as a skin sensitizer. A substance that causes immunological contact urticaria without meeting the criteria for a respiratory sensitizer can also be considered for classification as a skin sensitizer.

**10.4.2.3.2** There is no recognized animal model available to identify substances that cause immunological contact urticaria. Therefore, classification will normally be based on human evidence which will be similar to that for skin sensitization.

#### **10.4.2.4 Animal studies**

**10.4.2.4.1** When an adjuvant type test method for skin sensitization is used, a response of at least 30 % of the animals is considered as positive. For a non-adjuvant test method a response of at least 15 % of the animals is considered positive. Test methods for skin sensitization are described in OECD Test Guideline 406 and OECD Test Guideline 429 (see annex J). The Mouse Ear Swelling Test (MEST), is a reliable screening test to detect moderate to strong sensitizers, and can be used as a first stage in the assessment of skin sensitization potential. In the case of a positive result in the Mouse Ear Swelling Test it is not necessary to conduct a further guinea pig test (see annex J).

**10.4.2.4.2** When evaluating test data on skin sensitization, the rate at which animals are sensitized should be considered. The rate of sensitization reflects the sensitizing capacity of a substance in relation to its mildly irritating dose. However, the dose might vary between substances. A more appropriate evaluation of the sensitizing capacity of a substance could be carried out if the dose-response relationship is known for the substance. However, this is an area that needs further development.



### **10.4.3 Classification criteria for mixtures**

#### **10.4.3.1 Classification of mixtures when data are available for the complete mixture**

When reliable and good quality evidence from human experience or appropriate animal studies as described in the classification criteria for substances (see 10.4.1 and 10.4.2), is available for a mixture, then the mixture can be classified by weight of evidence evaluation of these data. However, when evaluating data on mixtures, care should be exercised that the dose used does not render the results inconclusive.

#### **10.4.3.2 Classification of mixtures when data are not available for the complete mixture: Bridging Principles**

##### **10.4.3.2.1 General**

Where the mixture itself has not been tested to determine its sensitizing properties, but there are sufficient data available on the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the bridging principles given in 10.4.3.2.2 to 10.4.3.2.5. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional animal testing.

##### **10.4.3.2.2 Dilution**

If a mixture is diluted with a substance that is not a sensitizer and is not expected to affect the sensitization of other ingredients, then the new mixture can be classified as equivalent to the original mixture.

##### **10.4.3.2.3 Batching**

The sensitizing properties of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by, or under the control of, the same manufacturer, unless there is reason to believe there is significant variation such that the sensitization of the batch has changed. If the latter occurs, a new classification is necessary.

##### **10.4.3.2.4 Substantially similar mixtures**

In the case of two mixtures (A + B) and (C + B) where

- a) the concentration of ingredient B is essentially the same in both mixtures,
- b) the concentration of ingredient A equals that of ingredient C,
- c) ingredient B is a sensitizer and ingredients A and C are not sensitizers,
- d) ingredient A and ingredient C are not expected to affect the sensitizing properties of ingredient B,  
and
- e) mixture (A + B) has been classified by testing,

then mixture (C + B) can be assigned the same hazard category as mixture (A + B).

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### 10.4.3.2.5 Aerosols

A mixture in aerosol form can be classified in the same hazard category as the tested non-aerosol form, provided that the added propellant does not affect the sensitizing properties of the mixture upon spraying.

### 10.4.3.3 Classification of mixtures when data are available for all components or only for some components of the mixture

A mixture shall be classified as a respiratory sensitizer or a skin sensitizer, as applicable, when at least one ingredient has been classified as a respiratory sensitizer or a skin sensitizer and is present at, or above, the concentration limits as shown in table 33.

**Table 33 — Cut-off values/concentration limits of ingredients of a mixture classified as skin sensitizers or respiratory sensitizers that trigger classification of a mixture**

1	2	3	4
Ingredient classified as:	Concentration of the ingredients that triggers classification of a mixture		
	%		
	Skin sensitizer	Respiratory sensitizer	
	All physical states	Solid or liquid	Gas
Skin sensitizer	≥ 0,1 (see NOTE 1)	—	—
	≥ 1,0 (see NOTE 2)	—	—
Respiratory sensitizer	—	≥ 0,1 (see NOTE 3)	≥ 0,1 (see NOTE 5)
	—	≥ 1,0 (see NOTE 4)	≥ 0,2 (see NOTE 6)
<p>NOTE 1 If a skin sensitizer is present in a mixture at a concentration between 0,1 % and 1,0 %, both an SDS and a label should be provided.</p> <p>NOTE 2 If a skin sensitizer is present in a mixture at a concentration of ≥ 1,0 %, both an SDS and a label should be provided.</p> <p>NOTE 3 If a solid or liquid respiratory sensitizer is present in a mixture at a concentration between 0,1 % and 1,0 %, both an SDS and a label should be provided.</p> <p>NOTE 4 If a solid or a liquid respiratory sensitizer is present in the mixture at a concentration of ≥ 1,0 %, both an SDS and a label should be provided.</p> <p>NOTE 5 If a gaseous respiratory sensitizer is present in the mixture at a concentration between 0,1 % and 0,2 %, both an SDS and a label should be provided.</p> <p>NOTE 6 If a gaseous respiratory sensitizer is present in the mixture at a concentration of ≥ 0,2 %, both an SDS and a label should be provided.</p>			

### 10.4.4 Hazard communication

The label elements for substances and mixtures that cause respiratory and skin sensitization are given in table 34. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*,

c) annex B, *Hazard communication and classification summary tables*.

**Table 34 — Label elements for respiratory sensitization and skin sensitization**

1	2	3
	<b>Respiratory sensitization Category 1</b>	<b>Skin sensitization Category 1</b>
<b>Symbol</b>	Health hazard	Exclamation mark
<b>Signal word</b>	Danger	Warning
<b>Hazard statement</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled	May cause an allergic skin reaction

## 10.5 Germ cell mutagenicity

### 10.5.1 General

**10.5.1.1** This hazard class covers chemicals that cause mutations in the germ cells of humans and that can be transmitted to the progeny.

**10.5.1.2** The term “mutation” (see 3.1.58) applies both to heritable genetic changes that can be manifested at the phenotypic level and to the underlying DNA modifications when known including, for example, specific base pair changes and chromosomal translocations. The terms “mutagenic” and “mutagen” (see 3.1.57) are used for agents giving rise to an increased occurrence of mutations in populations of cells or organisms (or both).

**10.5.1.3** The more general terms “genotoxic” and “genotoxicity” apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.

### 10.5.2 Classification criteria for substances

**10.5.2.1** A germ cell mutagen can be classified in one of two hazard categories according to the weight of evidence available (see table 35).

**10.5.2.2** For classification purposes, test results obtained by animal testing for mutagenic or genotoxic effects (or both) in germ cells or somatic cells (or both) shall be taken into account. Mutagenic or genotoxic effects (or both) determined in *in vitro* tests can also be used.

**10.5.2.3** The classification system is based on the intrinsic ability of a substance to induce mutations in germ cells and is not meant for the quantitative risk assessment of chemical substances.

**10.5.2.4** The classification of substances for heritable effects in human germ cells shall be made on the basis of well conducted, sufficiently validated tests (see 10.5.2.5 to 10.5.2.10, and annex J)). The test results shall be evaluated by using expert judgement and all available evidence shall be taken into account.

**10.5.2.5** *In vivo* heritable germ cell mutagenicity can be determined by OECD 478 or OECD 485.

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**10.5.2.6** *In vivo* somatic cell mutagenicity can be determined by OECD 474, OECD 475 or OECD 484.

**10.5.2.7** Germ cell mutagenicity shall be determined by OECD 483.

**10.5.2.8** Genotoxicity tests can be determined by means of sister chromatid exchange analysis in spermatogonia or the unscheduled DNA synthesis test (UDS) in testicular cells.

**10.5.2.9** Genotoxicity tests in somatic cells shall be determined by OECD 486.

**10.5.2.10** *In vitro* mutagenicity can be determined by OECD 471, OECD 473 or OECD 476.

**10.5.2.11** The classification of an individual substance shall be based on the total weight of evidence available, using expert judgement. In cases where a single well-conducted test is used for classification, it shall provide clear and unambiguously positive results. If new, well validated, tests arise these can also be used in the total weight of evidence to be considered. The relevance of the route of exposure used in the study of the chemical compared to the route of human exposure shall also be taken into account (see also 10.5.2.4).

**Table 35 — Hazard categories for germ cell mutagens**

1	2
Category	Classification criteria
1A	A substance known to induce heritable mutations in germ cells of humans: positive evidence from human epidemiological studies.
1B	A substance regarded to induce heritable mutations in the germ cells of humans: <ul style="list-style-type: none"> <li>a) positive results from <i>in vivo</i> heritable germ cell mutagenicity tests in mammals; or</li> <li>b) positive results from <i>in vivo</i> somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence can, for example, be derived from mutagenic or genotoxic tests in germ cells <i>in vivo</i>, or by demonstrating the ability of the substance or its metabolites to interact with the genetic material of the germ cells; or</li> <li>c) positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny, for example, an increase in the frequency of aneuploidy in sperm cells of exposed people.</li> </ul>
2 <sup>a</sup>	A substance that causes concern for humans owing to the possibility that it might induce heritable mutations in the germ cells of humans: <p>positive evidence from experiments in mammals and, in some cases from <i>in vitro</i> experiments, obtained from</p> <ul style="list-style-type: none"> <li>a) somatic cell mutagenicity tests <i>in vivo</i>, in mammals, or</li> <li>b) other <i>in vivo</i> somatic cell genotoxicity tests that are supported by positive results from <i>in vitro</i> mutagenicity assays.</li> </ul>
<sup>a</sup> Substances that are positive in <i>in vitro</i> mammalian mutagenicity assays, and also show a chemical structure activity relationship to known germ cell mutagens, should be considered for classification as category 2 mutagens.	

### **10.5.3 Classification criteria for mixtures**

#### **10.5.3.1 Classification of mixtures when data are available for the complete mixture**

The classification of a mixture shall be based on the available test data for the individual ingredients of the mixture using the cut-off values/concentration limits for the ingredients classified as germ cell mutagens. The classification can be modified on a case-by-case on account of the available test data for the mixture as a whole. In such a cases the test results for the mixture as a whole shall be conclusive when taking into account dose and other factors such as duration, observations and analysis (for example statistical analysis and test sensitivity) of germ cell mutagenicity test systems. Adequate documentation supporting the classification shall be retained and made available for review upon request.

#### **10.5.3.2 Classification of mixtures when data are not available for the complete mixture: Bridging principles**

##### **10.5.3.2.1 General**

Where the mixture itself has not been tested to determine its germ cell mutagenicity hazard, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the bridging principles given in 10.5.3.2.2 to 10.5.3.2.4. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional animal testing.

##### **10.5.3.2.2 Dilution**

If a mixture is diluted with a substance that is not expected to affect the germ cell mutagenicity of the other ingredients, then the new mixture can be classified as equivalent to the original mixture.

##### **10.5.3.2.3 Batching**

The germ cell mutagenic potential of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by, or under the control of, the same manufacturer, unless there is reason to believe there is significant variation in composition such that the germ cell mutagenic potential of the batch has changed. If the latter occurs, a new classification is necessary.

##### **10.5.3.2.4 Substantially similar mixtures**

In the case of two mixtures (A + B) and (C + B) where

- a) the concentration of mutagen ingredient B is the same in both mixtures,
- b) the concentration of ingredient A equals that of ingredient C,
- c) data on the toxicity for ingredient A and ingredient C are available and are substantially equivalent, that is, they are in the same hazard category and are not expected to affect the germ cell mutagenicity of ingredient B, and
- d) mixture (A + B) has been classified by testing,

then mixture (B + C) can be assigned the same hazard category as mixture (A + B).

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### 10.5.3.3 Classification of mixtures when data are available for all components or only for some components of the mixture

A mixture shall be classified as a mutagen when at least one ingredient has been classified as a category 1 or a category 2 mutagen and is present at, or above, the appropriate concentration limit as shown in table 36.

**Table 36 — Cut-off values/concentration limits of ingredients of a mixture classified as germ cell mutagens that trigger classification of the mixture**

1	2	3
Ingredient	Concentration of the ingredients that triggers classification of a mixture <sup>a</sup>	
	%	
	Category 1 mutagen	Category 2 mutagen
Category 1 mutagen	≥ 0,1	—
Category 2 mutagen	—	≥ 1,0
<sup>a</sup> The concentration limits apply to solids and liquids (expressed in % by mass) and to gases (expressed in % by volume).		

### 10.5.4 Hazard communication

The label elements for substances and mixtures that cause germ cell mutagenicity are given in table 37. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 37 — Label elements for germ cell mutagenicity**

1	2	3	4
	Category 1A	Category 1B	Category 2
Symbol	Health hazard	Health hazard	Health hazard
Signal word	Danger	Danger	Warning
Hazard statement	May cause genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	May cause genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	Suspected of causing genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

## 10.6 Carcinogenicity

### 10.6.1 Classification criteria for carcinogenic substances

**10.6.1.1** Classification of a substance as carcinogenic (see 3.1.13) is based on the inherent properties of a substance and does not provide information on the level of the human cancer risk which the use of the substance may present.

**10.6.1.2** For the purpose of classification for carcinogenicity, a chemical substance is allocated to one of two categories (see table 38) based on strength of evidence and additional considerations (weight of evidence). In certain instances, route specific classification may be warranted.

**Table 38 — Hazard categories for carcinogens**

1	2
Category	Classification criteria
1A	Known to have carcinogenic potential for humans. Based largely on human evidence.
1B	Presumed to have carcinogenic potential for humans: a) evidence from human studies that establish a causal relationship between human exposure to a chemical and the development of cancer (known human carcinogen); or b) evidence from animal tests for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen); and c) on a case-by-case basis, scientific judgement may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in animal tests.
2	Suspected human carcinogen: a) evidence obtained from human or animal studies (or both), but which is not sufficiently convincing for classification as a category 1 carcinogen; and b) limited evidence of carcinogenicity in human studies or limited evidence of carcinogenicity in animal tests.

**10.6.1.3** Classification as a carcinogen shall be based on evidence from reliable and acceptable methods that are intended to be used for chemicals which have an intrinsic property to produce carcinogenic effects. The evaluation shall be based on all existing data, peer-reviewed published studies and additional data accepted by regulatory agencies.

**10.6.1.4** The classification of a substance as a carcinogen is a criterion-based process that involves two interrelated determinations: evaluation of strength of evidence (see 10.6.1.5) and consideration of all other relevant information to place a chemical with human cancer potential into hazard categories.

**10.6.1.5** "Strength of evidence" involves the enumeration of tumours in human and animal studies and determination of their level of statistical significance. "Sufficient human evidence" demonstrates causality between human exposure and the development of cancer, whereas "sufficient evidence" in animals shows a causal relationship between the agent and an increased incidence of tumours.

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"Limited evidence" in humans is demonstrated by a positive association between exposure and cancer, but a causal relationship cannot be stated. "Limited evidence" in animals is provided when data suggest a carcinogenic effect, but are less than sufficient.

NOTE The terms "sufficient" and "limited" are used in this standard as defined by the International Agency for Research on Cancer (IARC).

**10.6.1.6** Apart from the strength of evidence for carcinogenicity, a number of other factors (additional considerations; weight of evidence) shall be taken into account to determine the overall likelihood of a substance to pose a carcinogenic hazard in humans. The factors (see 10.6.1.7 and 10.6.1.8) can be viewed as either increasing or decreasing the level of concern for human carcinogenicity. Generally, more complete information decreases, rather than increases, the level of concern. Additional considerations shall also be used in evaluating the tumour findings and the other factors in a case-by-case manner.

**10.6.1.7** The following factors shall be taken into account when assessing the overall level of concern for carcinogenicity:

- a) tumour type and background incidence;
- b) multisite responses;
- c) progression of lesions to malignancy; and
- d) reduced tumour latency.

**10.6.1.8** Additional factors which can increase or decrease the level of concern include:

- a) whether responses are in both sexes;
- b) whether responses are in a single species or several species;
- c) structural similarity, or not, to a chemical(s) for which there is good evidence of carcinogenicity;
- d) routes of exposure;
- e) comparison of absorption, distribution, metabolism and excretion between test animals and humans;
- f) the possibility of a confounding effect of excessive toxicity at test doses; and
- g) mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis (stimulation of cell division) and immuno suppression.

**10.6.1.9** It is recognized that genetic events are central in the overall process of cancer development. Therefore evidence of mutagenic activity *in vivo* can indicate that a chemical has a potential for carcinogenic effects.

**10.6.1.10** A chemical that has not been tested for carcinogenicity can, in certain instances, be classified in category 1 or category 2 based on tumour data from a structural analogue together with substantial support of other important factors such as formation of common significant metabolites, for example, for benzidine congener dyes.

**10.6.1.11** For classification purposes it shall also be taken into account whether a substance is absorbed by a given route(s); or whether there are only local tumours at the site of administration for the tested route(s), and whether testing by other major route(s) shows lack of carcinogenicity.



**10.6.1.12** Whatever is known of the physico-chemical, toxicokinetic and toxicodynamic properties of a substance, as well as any available relevant information on chemical analogues (structure activity relationship), shall be taken into account for classification purposes.

## **10.6.2 Classification criteria for mixtures**

### **10.6.2.1 Classification of mixtures when data are available for the complete mixture**

The classification of a mixture shall be based on the available test data of the individual ingredients of the mixture by using the cut-off values/concentration limits (see table 39) for those ingredients. The classification can be modified on a case-by-case basis on account of the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole shall be conclusive when taking into account dose and other factors such as duration, observations and analysis, for example, statistical analysis and test sensitivity. Adequate documentation supporting the classification shall be retained and made available for review upon request.

### **10.6.2.2 Classification of mixtures when data are not available for the complete mixture: Bridging principles**

#### **10.6.2.2.1 General**

Where the mixture itself has not been tested to determine its carcinogenic potential, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the agreed bridging principles given in 10.6.2.2.2 to 10.6.2.2.4. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional animal testing.

#### **10.6.2.2.2 Dilution**

If a mixture is diluted with a substance that is not expected to affect the carcinogenicity of the other ingredients, then the new mixture can be classified as equivalent to the original mixture.

#### **10.6.2.2.3 Batching**

The carcinogenic potential of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product produced by, or under the control of, the same manufacturer unless there is reason to believe there is significant variation in composition such that the carcinogenic potential of the batch has changed. If the latter occurs, a new classification is necessary.

#### **10.6.2.2.4 Substantially similar mixtures**

In the case of two mixtures (A + B) and (C + B) where

- a) the concentration of carcinogen ingredient B is the same in both mixtures,
- b) the concentration of ingredient A equals that of ingredient C,
- c) the toxicity data for ingredient A and ingredient C are available and substantially equivalent, that is, they are in the same hazard category and are not expected to affect the carcinogenicity of ingredient B, and
- d) mixture (A + B) has been classified by testing,

then mixture (C + B) can be assigned the same hazard category as mixture (A + B).

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### 10.6.2.3 Classification of mixtures when data are available for all components or only for some components of the mixture

A mixture shall be classified as a carcinogen when at least one ingredient has been classified as a category 1 or category 2 carcinogen and is present at, or above, the appropriate concentration limit as shown in table 39.

**Table 39 — Cut-off values/concentration limits of ingredients classified as carcinogens that trigger classification of the mixture**

1	2	3
Ingredient classified as:	Cut-off values/concentration limits of ingredients that trigger classification of a mixture	
	%	
	Category 1 carcinogen	Category 2 carcinogen
Category 1 carcinogen	≥ 0,1	
Category 2 carcinogen	–	≥ 0,1 <sup>a</sup>
		≥ 1,0 <sup>b</sup>
<sup>a</sup> If a category 2 carcinogen ingredient is present in the mixture at a concentration between 0,1 % and 1 %, a regulatory authority could require information on the SDS for a product. Some authorities might choose a warning on the label when the ingredient is present in the mixture between 0,1 % and 1 %, while other authorities would normally not require a label in this case.		
<sup>b</sup> If a category 2 carcinogen ingredient is present in the mixture at a concentration of ≥ 1 %, both an SDS and a label would generally be expected.		

### 10.6.3 Hazard communication

The label elements for carcinogenic substances are given in table 40. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 40 — Label elements for carcinogenicity**

1	2	3	4
	<b>Category 1A</b>	<b>Category 1B</b>	<b>Category 2</b>
<b>Symbol</b>	Health hazard	Health hazard	Health hazard
<b>Signal word</b>	Danger	Danger	Warning
<b>Hazard statement</b>	May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

## 10.7 Reproductive toxicity

### 10.7.1 General

Some reproductive toxic effects (see 3.1.70) cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nevertheless, chemicals with these effects should be classified as reproductive toxicants with a general hazard statement.

#### 10.7.1.2 Adverse effects on sexual function and fertility

**10.7.1.2.1** Adverse effects on sexual function and fertility include, but are not be limited to, alterations to the female and male reproductive system, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, ability to give birth, pregnancy outcomes, premature aging, or modifications in other functions that are dependent on the integrity of the reproductive systems.

**10.7.1.2.2** Adverse effects on, or via, lactation are also included in reproductive toxicity. However, for classification purposes such effects are treated separately (see 10.7.2.3) so that a specific hazard warning about this effect can be provided for lactating mothers.

#### 10.7.1.3 Adverse effects on development of the offspring

Developmental toxicity includes any effect which interferes with normal development of the offspring, either before or after birth and that results from exposure of either parent prior to conception, or exposure of the developing offspring during prenatal development, or postnatally, to the time of sexual maturation. However, developmental toxicity is primarily intended to provide a hazard warning for pregnant women, and for men and women of reproductive capacity. Therefore, for purposes of classification, developmental toxicity essentially means adverse effects induced during pregnancy, or as a result of parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include

- a) death of the developing organism,
- b) structural abnormality,
- c) altered growth, and
- d) functional deficiency.

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### 10.7.2 Classification criteria for substances

#### 10.7.2.1 Basis of classification

**10.7.2.1.1** The classification of a substance as a reproductive toxicant is based on appropriate criteria (see table 41) and an assessment of the total weight of evidence (see 10.7.2.4). Such chemicals have intrinsic, specific properties to produce adverse effects on reproduction and shall not be so classified if such effects are produced solely as a non-specific secondary consequence of other toxic effects.

**10.7.2.1.2** In the evaluation of toxic effects on the developing offspring, it is important to consider the possible influence of maternal toxicity (see 10.7.2.5).

**10.7.2.1.3** For human evidence to provide the primary basis for a category 1A classification), reliable evidence of adverse effects on reproduction in humans shall be available. Such evidence shall be from well conducted epidemiological studies which include the use of appropriate controls, balanced assessment, and due consideration of bias or confounding factors. Less rigorous data from studies in humans shall be supplemented with adequate data from studies in experimental animals for classification in category 1B.

#### 10.7.2.2 Hazard categories

For the purposes of classification for reproductive toxicity, a substance is allocated to one of two hazard categories (see table 41). Effects on lactation are allocated to a separate hazard category (see 10.7.2.3).

**Table 41 — Hazard categories for reproductive toxicants**

1	2	3
Hazard category	Adverse effects	Classification criteria
1A	Known to produce adverse effects on sexual function and fertility, or on the development of the offspring.	Based largely on human evidence.
1B	Presumed to have adverse effects on sexual function and fertility, or on the development of the offspring.	Based largely on evidence from animal tests. The data shall provide clear evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects. If occurring together with other toxic effects the adverse effect on reproduction shall not be considered a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect to humans, classification in category 2 is more appropriate.
2	Suspected adverse effects on sexual function and fertility.	Some evidence from human experience or animal tests, possibly supplemented with other information. In the absence of other toxic effects or, if occurring together with other toxic effects, the adverse effect on sexual function and fertility shall not be considered a non-specific consequence of the other toxic effects. Category 2 is appropriate where evidence is not sufficiently convincing for classification in category 1, for example, deficiencies in a study that make the quality of the evidence less convincing.

### **10.7.2.3 Hazard category for effects on, or via, lactation**

Adverse effects on, or via, lactation are allocated to a single hazard category. For many substances, no information is available on the potential to cause adverse effects on the offspring via lactation. However, substances that are known to interfere with lactation (including metabolites), or that can be present in breast milk in amounts sufficient to cause concern for the health of the breastfed child, shall be classified as hazardous via lactation. Classification can be assigned on the basis of the following:

- a) absorption, metabolism, distribution and excretion studies indicating the likelihood that the substance can be present at potentially toxic levels in breast milk; and/or
- b) results of one or two generation studies in animals that provide clear evidence of adverse effects in the offspring due to transfer in the milk, or adverse effects on the quality of the milk; and/or
- c) human evidence indicating a hazard to babies during the lactation period.

### **10.7.2.4 Weight of evidence**

**10.7.2.4.1** A substance is classified as a reproductive toxicant on the basis that all available reproductive toxicity information on the substance be considered together (total weight of evidence). Such information includes epidemiological studies, case reports in humans, specific reproduction studies, and sub-chronic, chronic and special study results in animals that provide relevant information regarding toxicity to reproductive and related endocrine organs. Evaluation of substances chemically related to the material in question may also be included, particularly when information on the material is scarce. The weight given to the available evidence will be influenced by factors such as the quality of the studies, consistency of results, nature and severity of effects, level of statistical significance for intergroup differences, number of endpoints affected, relevance of route of administration to humans, and impartiality. Both positive and negative results shall be assembled together into a weight of evidence determination. However, a single, positive study performed in accordance with good scientific principles and with statistically or biologically significant positive results could justify classification (see also 10.7.2.4.3).

**10.7.2.4.2** Toxicokinetic studies in animals and humans, site of action and mechanism, or mode of action study results, could provide relevant information to reduce or increase concerns about the hazards to human health. A substance that produces an adverse effect on reproduction in test animals need not be classified, provided that

- a) conclusive evidence shows that the identified mechanism or mode of action has no relevance for humans, or
- b) the toxicokinetic differences are so marked that the hazardous property will not be expressed in humans.

**10.7.2.4.3** If the only effects in animal tests on reproductive toxicity studies are considered of low or minimal toxicological significance, classification need not necessarily be the outcome. Effects of minimal toxicological significance include:

- a) small changes in semen parameters;
- b) the incidence of spontaneous defects in the foetus;
- c) small changes in the proportions of common foetal variants such as are observed in skeletal examinations or in foetal weights; or
- d) small differences in postnatal developmental assessments.

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**10.7.2.4.4** Data from animal tests should provide clear evidence of specific reproductive toxicity in the absence of other, systemic, toxic effects. However, if developmental toxicity occurs together with other toxic effects, the potential influence of the generalized adverse effects should be assessed. The preferred approach is to consider adverse effects in the embryo/foetus first, and then evaluate maternal toxicity along with any other factors that are likely to have influenced these effects, as part of the weight of evidence. In general, developmental effects observed at maternally toxic doses should not be automatically discounted. Discounting developmental effects observed at maternally toxic doses can only be done on a case-by-case basis when a causal relationship is established or refuted.

**10.7.2.4.5** For classification purposes, it is important to determine whether developmental toxicity is due to a specific maternally mediated mechanism or to a non-specific secondary mechanism, for example maternal stress and the disruption of homeostasis. In general, the presence of maternal toxicity should not be used to negate findings of embryo/foetal effects, unless it can be clearly demonstrated that the effects are secondary non-specific effects. This is especially the case when the effects in the offspring are significant, for example, irreversible effects such as structural malformations. In some situations it is reasonable to assume that reproductive toxicity is due to a secondary consequence of maternal toxicity and discount the effects, for example, if the chemical is so toxic that there is severe inanition (exhaustion from lack of nourishment), they are incapable of nursing pups; or they are prostrate or dying.

#### **10.7.2.5 Maternal toxicity**

**10.7.2.5.1** Development of the offspring throughout gestation and during the early postnatal stages can be influenced by toxic effects in the mother either through non-specific mechanisms related to stress and the disruption of maternal homeostasis, or by specific maternally-mediated mechanisms. This is a complex issue because of uncertainties surrounding the relationship between maternal toxicity and developmental outcome. For classification purposes, expert judgement and a weight of evidence approach, taking into account all available studies, should be used to determine the degree of influence attributed to maternal toxicity on developmental effects. The adverse effects in the embryo/foetus should be considered first and then maternal toxicity, along with any other factors that are likely to have influenced these effects.

**10.7.2.5.2** Depending on severity, maternal toxicity might influence development via non-specific secondary mechanisms, producing effects such as depressed foetal weight, retarded ossification, and possibly, resorption and certain malformations in some strains of certain species. However, the limited numbers of studies investigating the relationship between developmental effects and general maternal toxicity have failed to demonstrate a consistent, reproducible relationship across species. Developmental effects that occur in the presence of maternal toxicity are considered as evidence of developmental toxicity, unless it can be unequivocally demonstrated on a case-by-case basis that the developmental effects are secondary to maternal toxicity. Moreover, classification should be considered where there is significant toxic effects in the offspring, for example, irreversible effects such as structural malformations, embryo/foetal lethality and significant post-natal functional deficiencies.

**10.7.2.5.3** Classification should not automatically be discounted for chemicals that produce developmental toxicity only in association with maternal toxicity, even if a specific maternally-mediated mechanism has been demonstrated. In such a case, classification in category 2 could be more appropriate than category 1. However, when a chemical is so toxic that maternal death or severe inanition results in the mother being incapable of nursing the pups, it can be assumed that developmental toxicity is produced solely as a secondary consequence of maternal toxicity and the developmental effects can be discounted. Classification is not necessarily the outcome in the case of minor developmental changes, for example, a small reduction in foetal/pup body weight and retardation of ossification in association with maternal toxicity.

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**10.7.2.5.4** The end points used to assess maternal toxicity should be evaluated in light of their statistical or biological significance and dose response relationship. Some of the endpoints are listed in (a) to (h).

a) **Maternal mortality** – an increased incidence of mortality among the treated females over the control group can be considered evidence of maternal toxicity if the increase occurs in a dose-related manner and can be attributed to the systemic toxicity of the test material. A maternal mortality greater than 10 % is considered excessive and the data for that dose level should not normally be considered for further evaluation.

b) **Mating index** – number of test animals with seminal plugs or sperm/number of matings  $\times$  100.

c) **Fertility index** – number of test animals with implants/number of matings  $\times$  100.

NOTE The mating index and the fertility index can also be affected by the male.

d) **Gestation length** – if allowed to deliver.

e) **Body weight and body weight change** – consideration of the maternal body weight change and/or adjusted (corrected) maternal body weight should be included in the evaluation of maternal toxicity whenever such data are available. The calculation of an adjusted (corrected) mean maternal body weight change, which is the difference between the initial and terminal body weight minus the gravid uterine weight (or alternatively, the sum of the weights of the foetuses), may indicate whether the effect is maternal or intrauterine. In rabbits, the body weight gain is not a useful indicator of maternal toxicity because of normal fluctuations in body weight during pregnancy.

f) **Food and water consumption** (if relevant) – a significant decrease in the average food or water consumption in treated females compared to that of the control group can be used in evaluating maternal toxicity, particularly when the test material is administered in the diet or drinking water. Changes in food or water consumption should be evaluated in conjunction with maternal body weight in order to ascertain whether the effects are reflective of maternal toxicity or more simply, unpalatability of the test material in feed or water.

g) **Clinical evaluations** (including clinical signs, markers, haematology and clinical chemistry studies) –an increased incidence of significant clinical signs of toxicity in treated females relative to the control group can be used in evaluating maternal toxicity. If this is to be used as the basis for the assessment of maternal toxicity, the types, incidence, degree and duration of clinical signs shall be reported in the study. Examples of clinical signs of maternal toxicity include coma, prostration, hyperactivity, loss of righting reflex, ataxia, or laboured breathing.

h) **Post-mortem data** – increased incidence or severity of post-mortem findings (or both) can be indicative of maternal toxicity. This can include gross or microscopic pathological findings or organ weight data, for example, absolute organ weight, organ-to-body weight ratio, or organ-to-brain weight ratio. When supported by findings of adverse histopathological effects in the affected organ(s), the observation of a significant change in the average weight of suspected target organ(s) of treated females, compared to those in the control group, can be considered evidence of maternal toxicity.

### 10.7.2.6 Animal and experimental data

**10.7.2.6.1** OECD Test Guidelines shall be used for the determination of reproductive toxicity, for example OECD 414 for developmental toxicity, and OECD 415 and OECD 416 for one or two-generation toxicity (see annex J).



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**10.7.2.6.2** Results obtained from screening tests, for example OECD 421 and OECD 422, can be used to justify classification. However, the quality of this evidence is less reliable than that obtained through full studies.

**10.7.2.6.3** Adverse effects observed during short- or long-term repeated dose toxicity studies that are judged likely to impair sexual function and fertility, and that occur in the absence of significant generalised toxicity, can be used as a basis for classification, for example, histopathological changes in the gonads.

**10.7.2.6.4** Evidence from *in vitro* assays, or non-mammalian tests, and from analogous substances using structure-activity relationship (SAR), can be used for classification. In all cases of this nature, expert judgement shall be used to assess the adequacy of the data. Inadequate data shall not be used as a primary support for classification.

**10.7.2.6.5** Animal tests shall be conducted by routes of administration which relate to the potential route of human exposure. In practice, reproductive toxicity studies are conducted by using the oral route. However, if it can be conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it can be concluded that the hazardous property will not be expressed in humans, then a substance that produces an adverse effect on reproduction in experimental animals need not be classified.

**10.7.2.6.6** Studies involving routes of administration such as intravenous or intraperitoneal injection might result in exposure of the reproductive organs to unrealistically high levels of the test substance, or it might elicit local damage to the reproductive organs, for example by irritation. These effects should be interpreted with extreme caution and on their own would normally not be the basis for classification.

**10.7.2.6.7** Adverse effects on reproduction that are observed only at very high dose levels in animal studies, for example, doses that induce prostration, severe inappetence and excessive mortality, normally do not lead to classification. However, classification of a substance as a reproductive toxicant is appropriate if, for example, toxicokinetics information indicates that humans are more susceptible than animals (see also 10.7.2.5).

**10.7.2.6.8** The actual "limit dose" depends upon the test method that has been employed to provide the test results. For example, for repeated dose toxicity studies by the oral route in accordance with OECD 422 (see annex J), an upper dose level of 1000 mg/kg is used as the recommended limit dose, unless expected human response indicates the need for a higher dose level.

### **10.7.3 Classification criteria for mixtures**

#### **10.7.3.1 Classification of mixtures when data are available for the complete mixture**

The classification of a mixture shall be based on the available test data of the individual ingredients of the mixture by using the cut-off values/concentration limits (see table 42) for those ingredients. The classification can be modified on a case-by-case basis taking into account the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole shall be conclusive, when taking into account dose and other factors such as duration, observations and analysis, for example, statistical analysis and test sensitivity of the reproduction test systems. Adequate documentation supporting the classification shall be retained and made available for review upon request.



### **10.7.3.2 Classification of mixtures when data are not available for the complete mixture: Bridging principles**

#### **10.7.3.2.1 General**

Where the mixture itself has not been tested to determine its reproductive toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterise the hazards of the mixture, these data shall be used in accordance with the bridging principles given in 10.7.3.2.2 to 10.7.3.2.4. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional animal testing.

#### **10.7.3.2.2 Dilution**

If a mixture is diluted with a substance that is not expected to affect the reproductive toxicity of other ingredients, then the new mixture can be classified as equivalent to the original mixture.

#### **10.7.3.2.3 Batching**

The reproductive toxicity potential of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product produced by, and under the control of, the same manufacturer unless there is reason to believe that there is a significant variation in composition such that the reproductive toxicity potential of the batch has changed. If the latter occurs, a new classification is necessary.

#### **10.7.3.2.4 Substantially similar mixtures**

In the case of two mixtures (A + B) and (C + B) where:

- a) the concentration of ingredient B, toxic to reproduction, is the same in both mixtures;
- b) the concentration of ingredient A equals that of ingredient C;
- c) the toxicity data for ingredient A and ingredient C are available and substantially equivalent, that is, they are in the same hazard category and are not expected to affect the reproductive toxicity of ingredient B; and
- d) mixture (A + B) has already been classified by testing,

then mixture (C + B) can be assigned the same hazard category as mixture (A + B).

### **10.7.3.3 Classification of mixtures when data are available for all components or only for some components of the mixture**

A mixture shall be classified as a reproductive toxicant when at least one ingredient has been classified as a category 1 or a category 2 reproductive toxicant and is present at, or above, the appropriate concentration limit as shown in table 42.

A mixture shall be classified for effects on, or via, lactation when at least one ingredient has been classified for effects on, or via, lactation and is present at or above the appropriate cut-off value/concentration limit as shown in table 42.

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**Table 42 — Cut-off values/concentration limits of the ingredients of a mixture classified as reproductive toxicants or for effects on, or via, lactation that trigger classification of the mixture**

1	2	3	4
Ingredients classified as:	Cut-off values/concentration limits of the ingredients that trigger classification of a mixture		
	%		
	Category 1 reproductive toxicant	Category 2 reproductive toxicant	Additional category for effects on, or via, lactation
Category 1 reproductive toxicant	≥ 0,1 (see NOTE 1)		
	≥ 0,3 (see NOTE 2)		
Category 2 reproductive toxicant		≥ 0,1 (see NOTE 3)	
		≥ 3,0 (see NOTE 4)	
Additional category for effects on, or via, lactation			≥ 0,1 (see NOTE 1)
			≥ 0,3 (see NOTE 2)
<p>NOTE 1 If a category 1 reproductive toxicant or a substance classified in the additional category for effects on, or via, lactation is present in the mixture at a concentration between 0,1 % and 0,3 %, an SDS is required for such a product. However, a warning on the label is optional.</p> <p>NOTE 2 If a category 1 reproductive toxicant or a substance classified in the additional category for effects on, or via, lactation is present in the mixture at a concentration equal to or more than 0,3 %, an SDS is required for such a product as well as a warning on the label.</p> <p>NOTE 3 If a category 2 reproductive toxicant is present in a mixture at a concentration between 0,1 % and 3,0 %, an SDS is required for such a product. However, a warning on the label is optional.</p> <p>NOTE 4 If a category 2 reproductive toxicant is present in a mixture at a concentration equal to or more than 3,0 %, an SDS is required for such a product as well as a warning on the label.</p>			

### 10.7.4 Hazard communication

The label elements for substances and mixtures classified as reproductive toxicants or for effects on, or via, lactation are given in table 43. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 43 — Label elements for reproductive toxicity**

1	2	3	4	5
	<b>Category 1A</b>	<b>Category 1B</b>	<b>Category 2</b>	<b>Additional category for effects on, or via, lactation</b>
<b>Symbol</b>	Health hazard	Health hazard	Health hazard	No symbol
<b>Signal word</b>	Danger	Danger	Warning	No signal word
<b>Hazard statement</b>	May damage fertility or the unborn child (state specific effect if known) or (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	May damage fertility or the unborn child (state specific effect if known) or (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	Suspected of damaging fertility or the unborn child (state specific effect if known) or (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	May cause harm to breast-fed babies.

## 10.8 Specific target organ toxicity — single exposure

### 10.8.1 General

**10.8.1.1** Classification of a substance or a mixture as a specific target organ toxicant – single exposure, depends upon the availability of reliable evidence that a single exposure to the substance or mixture has caused

- a) consistent and identifiable toxic effects in humans and test animals,
- b) toxicologically significant changes that have affected the function or morphology of tissue or an organ (or both), or
- c) serious changes to the biochemistry or haematology of the organism that are relevant for human health.

**10.8.1.2** Human data shall be the primary source of evidence for classification of a substance or a mixture as a specific target organ toxicant – single exposure.

**10.8.1.3** Assessment shall not only take into account significant changes in a single organ or a biological system but also generalised changes of a less severe nature involving several organs.

**10.8.1.4** Specific target organ toxicity can occur by any route that is relevant for humans, that is, oral, dermal or inhalation.

**10.8.1.5** The relevant route of exposure by which a substance produces specific target organ toxicity shall be identified.

**10.8.1.6** The classification criteria of a substance or a mixture for specific target organ toxicity – single exposure, are given in table 44.

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**Table 44 — Hazard categories for specific target organ toxicity — single exposure**

1	2	3
Hazard category	Adverse effects	Classification criteria
1	Significant toxicity in humans	a) Reliable evidence from human cases; or b) epidemiological studies; or c) observations from appropriate studies in test animals in which significant or severe toxic effects (or both) of relevance to human health were caused at low concentrations of exposure (see table 45).
2	Harmful to human health	a) Observations from appropriate animal tests in which significant toxic effects of relevance to human health were caused at moderate exposure concentrations (see table 45); or b) human evidence (only in exceptional cases).
3	Transient target organ effects	Effects that adversely alter human function for a short duration after exposure and from which humans recover in a reasonable period without leaving significant alteration of structure or function. These effects include narcotic effects and respiratory tract irritation (see 10.8.2.2).
NOTE For these hazard categories, the specific target organ that has been primarily affected by the substance should be identified, or the substance could be identified as a general organ toxicant. Attempts should be made to determine the primary target organ of toxicity and classify for that purpose, for example, hepatotoxicants and neurotoxicants. Data should be carefully evaluated and, where possible, secondary effects should not be considered, for example, a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems.		

### 10.8.2 Classification criteria for substances

#### 10.8.2.1 Substances of category 1 and category 2

##### 10.8.2.1.1 General

**10.8.2.1.1.1** A substance shall be classified for immediate or delayed effects separately, by the use of expert judgement on the basis of the total weight of evidence, including:

- a) data on incidents affecting humans;
- b) epidemiology;
- c) studies conducted in test animals; and
- d) the recommended guidance values (see 10.8.2.1.4 and table 45).

**10.8.2.1.1.2** Specific target organ toxicants are allocated to hazard category 1 or hazard category 2 depending on the nature and the severity of the effect(s) observed.

**10.8.2.1.1.3** The information required to evaluate specific target organ toxicity can be obtained from single exposure in humans, for example, exposure at home, in the workplace, environmentally, or from studies conducted with test animal studies and which include clinical observations and detailed haematological, macroscopic and microscopic examination to enable identification of the toxic effects on target tissue or target organs. Data obtained from acute toxicity studies in other species might also provide relevant information.

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**10.8.2.1.1.4** In exceptional cases, based on expert judgement, a substance with human evidence of target organ toxicity can be allocated to category 2, for example, when the weight of human evidence is not sufficiently convincing to warrant category 1 classification, or based on the nature and severity of the adverse effects (or both). Dose/concentration levels in humans shall not be taken into account for classification and any available evidence from animal tests shall be consistent with the category 2 classification. In other words, if there are also animal data available on the chemical that warrant category 1 classification, the chemical shall be classified as category 1.

### **10.8.2.1.2 Effects that justify classification in category 1 and category 2**

**10.8.2.1.2.1** Evidence associating a single exposure to a substance with a consistent and identifiable toxic effect, demonstrates support for classification.

**10.8.2.1.2.2** Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and might not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

**10.8.2.1.2.3** Evidence from animal tests can furnish detail on specific target organ toxicity – single exposure in the form of clinical observations, and macroscopic and microscopic pathological examinations. Such information often reveals hazards that are not life-threatening but indicate functional impairment. Consequently, all available evidence, and its relevance to human health, shall be taken into account for the classification process. Examples of relevant toxic effects in humans or animals (or both) are:

- a) morbidity resulting from a single exposure;
- b) significant functional changes in the central or peripheral nervous systems or other organ systems, including signs of central nervous system depression and effects on the senses, for example, sight, hearing and smell;
- c) any consistent and significant adverse changes in clinical biochemistry, haematology, or urinalysis parameters;
- d) significant organ damage observed during an autopsy and that is subsequently confirmed by a microscopic examination;
- e) multifocal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;
- f) morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction like fatty change in the liver; and
- g) evidence of appreciable necrosis (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

### **10.8.2.1.3 Effects that do not justify classification in category 1 and category 2**

Effects observed in humans or animals (or both), that do not justify classification include the following:

- a) clinical observations or small changes in body mass, food consumption and water intake might have some toxicological importance but do not, by themselves, indicate "significant" toxicity;
- b) small changes in clinical biochemistry, haematology or urinalysis parameters, or transient effects, when such changes or effects are of doubtful or minimal toxicological importance;

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- c) changes in organ weight with no evidence of organ dysfunction;
- d) adaptive responses that are not considered toxicologically relevant; and
- e) substance-induced species-specific mechanisms of toxicity that demonstrate with reasonable certainty not to be relevant for human health.

### 10.8.2.1.4 Guidance values to assist with classification for category 1 and category 2 based on the results obtained from animal testing

**10.8.2.1.4.1** Dose/concentration values that are known to produce significant specific target organ toxicity after a single exposure are given in table 45 as “guidance values” to assist with the classification of substances. Guidance values are a useful tool for the classification of substances since all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged.

NOTE The guidance values are not intended as strict demarcation values.

**10.8.2.1.4.2** When significant toxic effects in animal studies indicate classification, consideration of the dose/concentration at which these effects occurred in relation to the suggested guidance values, can provide useful information to help assess the need for classification. The reason for this is that toxic effects are a consequence of the hazardous property(ies) of a substance and also the dose/concentration.

**10.8.2.1.4.3** The guidance values proposed for single-dose exposure (see table 45) are applicable to acute toxicity testing that has produced a significant non-lethal toxic effect.

**Table 45 — Guidance values for single-dose exposures**

1	2	3	4	5
Route of exposure	Units	Guidance value ranges for:		
		Category 1	Category 2	Category 3
Oral (rat)	mg/kg body mass	$C \leq 300$	$2000 \geq C > 300$	Guidance values do not apply <sup>a</sup>
Dermal (rat or rabbit)	mg/kg body mass	$C \leq 1000$	$2000 \geq C > 1000$	
Inhalation (rat) gas	ppm	$C \leq 2500$	$5000 \geq C > 2500$	
Inhalation (rat) vapour	mg/L	$C \leq 10$	$20 > C > 10$	
Inhalation (rat) dust/mist/fume	mg/L/4h	$C \leq 1,0$	$5,0 > C > 1,0$	
<sup>a</sup> Guidance values are not given since classification in category 3 is primarily based on human data. Animal data may be included in the weight of evidence evaluation.				

**10.8.2.1.4.4** It is possible that a specific profile of toxicity could occur at a dose/concentration below the guidance value, for example oral toxicity of less than 2 000 mg/kg body mass. However, the nature of the effect might result in a decision not to classify. Conversely, a specific profile of toxicity could be observed in animal studies at, or above a guidance value, for example, an oral toxicity at or above 2 000 mg/kg body mass. In addition, supplementary information from other sources such as other single dose studies or human case experience could support a conclusion that, in view of the weight of evidence, classification is the prudent action to take. Guidance values are **not** intended as strict demarcation values.

#### **10.8.2.1.5 Other considerations**

**10.8.2.1.5.1** The classification of a substance based only on animal data (typical of new chemicals, but also true for many existing chemicals), shall include reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

**10.8.2.1.5.2** Classification is justified by well-substantiated human data showing a specific target organ toxic effect that can be reliably attributed after a single exposure to the substance. Positive human data, regardless of probable dose, takes precedence over animal data. Thus, if a substance has not been classified because a specific target organ systemic toxicity was considered irrelevant or not significant to humans, but subsequent human incident data become available that show a specific target organ systemic toxic effect, then such a substance needs to be classified.

**10.8.2.1.5.3** A substance not tested for specific target organ toxicity should be classified on the basis of data from a validated structure activity relationship and expert judgement-based extrapolation from a structural analogue that has previously been classified, together with other factors such as the formation of common significant metabolites.

**10.8.2.1.5.4** Saturated vapour concentration could be used as an additional element to provide for specific health and safety protection.

#### **10.8.2.2 Substances of category 3**

##### **10.8.2.2.1 Criteria for respiratory tract irritation**

The criteria for a substance to be classified as a respiratory tract irritant of hazard category 3 are given in (a) to (e).

- a) Respiratory irritant effects based primarily on human data and characterized by localized redness, edema, severe itching or pain (or both) that impair function with symptoms such as cough, pain, choking, and breathing difficulties.
- b) Subjective human observations supported by objective measurements of clear respiratory tract irritation (RTI), for example electrophysiological responses and biomarkers of inflammation in nasal or bronchoalveolar lavage fluids.
- c) Symptoms in humans typical of those that would be produced in the exposed population rather than being an isolated idiosyncratic reaction or response triggered only in individuals with hypersensitive airways. Ambiguous reports simply of "irritation" shall be excluded as this term is commonly used to describe a wide range of sensations such as smell, unpleasant taste, a tickling sensation and dryness that are outside the scope of this classification endpoint.
- d) Animal studies that provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc) and histopathology (hyperemia, edema, minimal inflammation, thickened mucous layer). These effects are reversible and might be reflective of the characteristic clinical symptoms. Such animal studies can be used as part of weight of evidence evaluation.

**NOTE** There are currently no validated animal tests that deal specifically with RTI. However, useful information could be obtained from single and repeated inhalation toxicity tests.

- e) Classification only when more severe organ/systemic effects, including in the respiratory system, are not observed.



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### **10.8.2.2.2 Criteria for narcotic effects**

The criteria for a substance to be classified in hazard category 3 due to narcotic effects are given in (a) and (b).

- a) Central nervous system depression including narcotic effects in humans such as drowsiness, narcosis, reduced alertness, loss of reflexes, lack of coordination, and vertigo. These effects can also be manifested as severe headaches or nausea, and can lead to reduced judgement, dizziness, irritability, fatigue, impaired memory function, deficits in perception and coordination, reaction time, or sleepiness.
- b) Narcotic effects observed in animal studies such as lethargy, lack of coordination righting reflex, narcosis, and ataxia (loss of full control of bodily movements). However, if these effects are not of a temporary nature, the substance shall be classified as hazard category 1 or hazard category 2, as applicable.

### **10.8.3 Classification criteria for mixtures**

#### **10.8.3.1 General**

The same criteria as for substances are applied for the classification of mixtures for specific target organ systemic toxicity – single exposure, or alternatively, as described in 10.8.3.2 to 10.8.3.4.

#### **10.8.3.2 Classification of mixtures when data are available for the complete mixture**

When reliable and good quality evidence from human experience or appropriate animal testing as described in the classification criteria for substances (see 10.8.2), is available for a mixture, then the mixture can be classified by weight of evidence evaluation of this data. Care should be exercised when evaluating data on mixtures to ensure that dose, duration, observation or analysis, do not render the results inconclusive.

#### **10.8.3.3 Classification of mixtures when data are not available for the complete mixture: Bridging principles**

##### **10.8.3.3.1 General**

Where the mixture itself has not been tested to determine its target organ systemic toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the bridging principles given in 10.8.3.3.2 to 10.8.3.3.7. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity of additional animal testing.

##### **10.8.3.3.2 Dilution**

If a mixture is diluted with a substance that has the same or a lower toxicity classification as the least toxic original ingredient and that is not expected to affect the toxicity of other ingredients, then the new mixture is classified as equivalent to the original mixture.

##### **10.8.3.3.3 Batching**

The specific target organ toxicity – single exposure, of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by, or under the control, of the same manufacturer unless there is reason to believe that there is significant variation such that the toxicity potential of the batch has changed. If the latter occurs, a new classification is necessary.



#### **10.8.3.3.4 Concentration of highly toxic mixtures**

In the case of a highly toxic mixture of category 1 where the concentration of a toxic ingredient of the mixture is increased, such a concentrated mixture shall be classified in category 1 without additional testing.

#### **10.8.3.3.5 Interpolation within one hazard category**

For three mixtures with identical ingredients, where mixture A and mixture B are in the same hazard category, and mixture C contains the same toxicologically active ingredients with concentrations intermediate to the concentrations of those ingredients in mixtures A and B, then mixture C is assumed to be in the same hazard category as mixture A and mixture B.

#### **10.8.3.3.6 Substantially similar mixtures**

In the case of two mixtures (A + B) and (C + B) where

- a) the concentration of ingredient B is essentially the same in both mixtures,
- b) the concentration of ingredient A equals that of ingredient C,
- c) the toxicity data for ingredient A and ingredient C are available and substantially equivalent, that is, they are in the same hazard category and are not expected to affect the toxicity of ingredient B, and
- d) mixture (A + B) has already been classified by testing,

then mixture (C + B) can be assigned the same category as that of mixture (A + B).

#### **10.8.3.3.7 Aerosols**

For oral and dermal toxicity, a mixture in aerosol form can be classified in the same hazard category as the tested non-aerosol form, provided that the added propellant does not affect the toxicity of the mixture upon spraying. For inhalation toxicity, the classification of a mixture in aerosol form and that of the tested non-aerosol form should be considered separately.

#### **10.8.3.4 Classification of mixtures when data are available for all components or only for some components of the mixture**

**10.8.3.4.1** When no reliable evidence or test data are available on a mixture and the bridging principles (see 10.8.3.3.2 to 10.8.3.3.7) cannot be used for classification, the classification of the mixture shall be based on the classification of the ingredient substances. In such a case, the mixture shall be classified as a target organ toxicant (specific organ specified), following single exposure or repeated exposure (or both), when at least one ingredient

- a) has been classified as a category 1 or a category 2 target organ systemic toxicant, and
- b) is present at, or above, the appropriate cut-off/concentration limit as given in table 46 for hazard category 1 and hazard category 2 respectively.

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**Table 46 — Concentration limits/cut-off values of ingredients of a mixture classified as aspecific target organ toxicant that trigger classification of the mixture**

1	2	3
Hazard category of the ingredients	Cut-off values/concentration limits of ingredients of a mixture that trigger classification as a specific target organ toxicant – single exposure	
	%	
	Category 1	Category 2
Category 1	$\geq 1,0$ (see NOTE 1) $\geq 10$ (see NOTE 2)	
Category 2		$\geq 1,0$ (see NOTE 3) $\geq 10$ (see NOTE 4)
<p>NOTE 1 If a category 1 specific target organ toxicant is present in the mixture at a concentration between 1,0 % and 10 %, an SDS is required for such a mixture. However, a warning on the label is optional.</p> <p>NOTE 2 If a category 1 specific target organ toxicant is present in the mixture at a concentration equal to or more than 10 %, an SDS is required for such a mixture as well as a warning on the label.</p> <p>NOTE 3 If a category 2 specific target organ toxicant is present in the mixture at a concentration between 1,0 % and 10 %, an SDS is required for such a mixture. However, a warning on the label is optional.</p> <p>NOTE 4 If a category 2 specific target organ toxicant is present in the mixture at a concentration equal to or more than 10 %, an SDS is required for such a mixture as well as a warning on the label.</p>		

**10.8.3.4.2** The cut-off values/concentration limits and consequent classifications as given in table 46 shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants (see also 10.9).

**10.8.3.4.3** A mixture shall be classified for single- or repeated-dose toxicity (or both) independently.

**10.8.3.4.4** When toxicants that affect more than one organ are combined, the potentiation or synergistic interactions should be considered as certain substances cause target organ toxicity at concentrations lower than 1 % when other ingredients in the mixture might be known to potentiate its toxic effect.

**10.8.3.4.5** Care should be exercised when extrapolating the toxicity of a mixture that contains (an) ingredient(s) of hazard category 3 (see 10.8.2.2). A cut-off value/concentration limit of 20 % has been suggested; however, it should be recognized that the cut-off value/concentration might be higher or lower depending on the hazard category 3 ingredient(s). Some effects such as respiratory tract irritation might not occur below a certain concentration while other effects such as narcotic effects might occur below the 20 % value. It is therefore necessary that expert judgement be exercised.

#### 10.8.4 Hazard communication

The label elements for substances and mixtures that are classified as specific target organ toxicants after a single exposure are given in table 47. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 47 — Label elements for target organ toxicity — single exposure**

1	2	3	4
	<b>Category 1</b>	<b>Category 2</b>	<b>Category 3</b>
<b>Symbol</b>	Health hazard	Health hazard	Exclamation mark
<b>Signal word</b>	Danger	Warning	Warning
<b>Hazard statement</b>	Causes damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	May cause respiratory irritation <b>or</b> May cause drowsiness and dizziness

### 10.9 Specific target organ toxicity — repeated exposure

#### 10.9.1 General

**10.9.1.1** Classification of a substance or a mixture as a specific target organ toxicant – repeated exposure, depends upon the availability of reliable evidence that repeated exposure to the substance or mixture has caused

- a) consistent and identifiable toxic effect in humans and test animals,
- b) toxicologically significant changes that have affected the function or morphology of a tissue or an organ (or both), or
- c) serious changes to the biochemistry or haematology of the organism that are relevant for human health.

**10.9.1.2** Human data shall be the primary source of evidence for classification of a substance or a mixture as a specific target organ toxicant – repeated exposure.

**10.9.1.3** Assessment shall not only take into consideration significant changes in a single organ or a biological system but also changes of a less severe nature involving several organs.

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**10.9.1.4** The relevant route of exposure by which a substance produces specific target organ toxicity after repeated exposure shall be identified. Specific target organ toxicity in humans occurs mainly by ingestion, skin contact and inhalation.

### 10.9.2 Classification criteria for substances

#### 10.9.2.1 General

**10.9.2.1.1** A substance shall be classified as a specific target organ toxicant – repeated exposure by means of expert judgement on the basis of the total weight of evidence, including:

- a) data on incidents affecting humans;
- b) epidemiology;
- c) studies conducted in test animals; and
- d) the recommended guidance values (see 10.9.2.4, table 49 and table 50).

**10.9.2.1.2** Specific target organ toxicants – repeated exposure, are allocated to one of two hazard categories, depending on the nature and severity of the effect(s) observed (see table 48).

**Table 48 — Categories for specific target organ toxicity — repeated exposure**

1	2	3
Hazard category	Adverse effects	Classification criteria
1	Significant toxicity in humans	<ul style="list-style-type: none"> <li>a) Reliable evidence from human cases; or</li> <li>b) epidemiological studies; or</li> <li>c) observations from appropriate animal tests in which significant or severe toxic effects (or both) of relevance to human health were caused at low concentrations of exposure (see 10.9.2.4 and table 49).</li> </ul>
2	Harmful to human health	<ul style="list-style-type: none"> <li>a) Observations from appropriate animal tests in which significant toxic effects of relevance to human health were caused at low concentrations of exposure (see 10.9.2.4 and table 50); or</li> <li>b) human evidence (only in exceptional cases).</li> </ul>
<p>NOTE For both hazard categories, the specific target organ that has been primarily affected by the substance needs to be identified, or the substance could be identified as a general systemic toxicant. Attempts should be made to determine the primary target organ of toxicity and to classify for that purpose, for example, hepatotoxicants and neurotoxicants. Data should be carefully evaluated and, where possible, secondary effects should not be considered, for example, a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems.</p>		

**10.9.2.1.3** The information required to evaluate specific target organ toxicity can be obtained from repeated exposure in humans, for example exposure at home, in the workplace, or environment, or from studies conducted with test animals. The standard animal tests are performed with both male and female young albino rats over a period of 28 d, 90 d or the lifetime of the test animal (up to 2 years) and include clinical observations and detailed haematological, macroscopic and microscopic examinations to enable identification of the toxic effects on target tissue or target organs. Data

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obtained from studies in other species may also be used. Other long-term exposure studies, for example for carcinogenicity, neurotoxicity or reproductive toxicity, could also provide evidence of specific target organ toxicity to be used in the assessment of classification.

**10.9.2.1.4** In exceptional cases, based on expert judgement, a substance with human evidence of target organ toxicity can be allocated to category 2, for example when the weight of human evidence or the nature and severity of effects (or both) is not sufficiently convincing to warrant category 1 classification. Dose/concentration levels in humans shall not be considered for classification and any available evidence from animal studies shall be consistent with the category 2 classification. In other words, if there are also animal data available on the chemical that warrant category 1 classification, the chemical shall be classified as category 1.

### **10.9.2.2 Effects that justify classification**

**10.9.2.2.1** Evidence associating repeated exposure to a substance with a consistent and identifiable toxic effect, justifies classification.

**10.9.2.2.2** Evidence from human experience or incidents (or both) is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions and might not provide the scientific detail obtained from well conducted animal tests. Evidence from animal tests could furnish more detail in the form of clinical observations, and macroscopic and microscopic pathological examinations. Such information often reveals hazards that are not life-threatening but cause functional impairment. Consequently, all available evidence and its relevance to human health shall be taken into account in the classification process. Examples of relevant toxic effects in humans or animals (or both) are:

- a) morbidity or death resulting from repeated or long-term exposure even at relatively low doses/concentrations. These effects could be caused by bioaccumulation of the substance or its metabolites, or the overwhelming of the de-toxification process by repeated exposure;
- b) significant functional changes in the central or peripheral nervous systems or other organs, including signs of central nervous system depression and effects on the senses, for example, sight, hearing and smell;
- c) any consistent and significant adverse change in clinical biochemistry, haematology, or urinalysis parameters;
- d) significant organ damage observed during an autopsy and that is subsequently confirmed by a microscopic examination;
- e) multifocal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;
- f) morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction like fatty change in the liver; and
- g) evidence of appreciable necrosis (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

### **10.9.2.3 Effects that do not justify classification**

Effects observed in humans or animals (or both) that do not justify classification are the following:

- a) clinical observations or small changes in body mass, food consumption and water intake might have some toxicological importance but do not, by themselves, indicate "significant" toxicity;

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- b) small changes in clinical biochemistry, haematology or urinalysis parameters, or transient effects, when such changes or effects are of doubtful or minimal toxicological importance;
- c) changes in organ mass with no evidence of organ dysfunction;
- d) adaptive responses that are not considered toxicologically relevant; and
- e) substance-induced species-specific mechanisms of toxicity that demonstrate with reasonable certainty not to be relevant for human health

### 10.9.2.4 Guidance values to assist with classification based on the results obtained from animal tests

**10.9.2.4.1** In studies conducted with test animals, observation of effects alone without taking into account the duration of experimental exposure and dose/concentration, negates a fundamental concept of toxicology, namely, that all substances are potentially toxic. The effects of toxicity are the function of the dose/concentration and the duration of exposure to a substance. Most test guidelines for animal testing use an upper limit dose value.

**10.9.2.4.2** Dose/concentration values that produce significant specific target organ toxicity after repeated exposure with test animals are used as “guidance values” to assist in the classification of substances (see table 49 and table 50). Guidance values are a useful tool for the classification of substances since all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged. Also, repeated-dose studies conducted with test animals are designed to produce toxicity at the highest dose used in order to optimise the test objective. Therefore, not only the effects but also the dose/concentration that triggered the effects and the relevance for humans are to be taken into account.

**10.9.2.4.3** When significant toxic effects in animal studies are observed, the duration of experimental exposure and the dose/concentration at which these effects occurred in relation to the suggested guidance values, provide useful information to assess the need for classification. The reason for this is that toxic effects are a consequence of the hazardous property(ies) of a substance, the duration of exposure and the dose/concentration.

**10.9.2.4.4** The decision to classify can be influenced by the dose/concentration guidance values at, or below, which a significant toxic effect has been observed.

**10.9.2.4.5** The guidance values given in table 49 and table 50 are based on effects observed in a standard 90 d toxicity study conducted on rats (see also 10.9.2.1.3). The values can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration; for example for a 28 d study, the guidance values are to be increased by a factor of three.

**Table 49 — Guidance values to assist in category 1 classification**

1	2	3
Route of exposure	Unit	Guidance value (dose/concentration)
Oral (rat)	mg/kg body mass/d	10
Dermal (rat or rabbit)	mg/kg body mass/d	20
Inhalation (rat) gas	ppm/6h/d	50
Inhalation (rat) vapour	mg/L/6h/d	0,2
Inhalation (rat) dust/mist/fume	mg/L/6h/d	0,02

**Table 50 — Guidance values to assist in category 2 classification**

1	2	3
Route of exposure	Unit	Guidance value (dose/concentration)
Oral (rat)	mg/kg body mass/d	10 – 100
Dermal (rat or rabbit)	mg/kg body mass/d	20 – 200
Inhalation (rat) gas	ppm/6h/d	50 – 250
Inhalation (rat) vapour	mg/L/6h/d	0,2 – 1,0
Inhalation (rat) dust/mist/fume	mg/L/6h/d	0,02 – 0,2

**10.9.2.4.6** The guidance values given in table 49 and table 50 are intended only for guidance purposes as part of the weight of evidence approach and to assist with decisions about classification. They are **not** intended as strict demarcation values.

**10.9.2.4.7** It is possible that a specific profile of toxicity is observed in repeat-dose animal studies at a dose/concentration below the guidance value, for example, oral toxicity of less than 100 mg/kg body mass/d but that the nature of the effect, for example, nephrotoxicity observed only in male rats of a particular strain known to be susceptible to this effect, leads to a decision not to classify. Conversely, a specific profile of toxicity could be observed in animal studies at a guidance value, for example an oral toxicity at or above 100 mg/kg body mass/d. In addition, supplementary information from other sources, such as other long-term administration studies or human case experience could support a conclusion that, in view of the weight of evidence, classification is the prudent action to take.

#### **10.9.2.5 Other considerations**

**10.9.2.5.1** The classification of a substance based only on animal data (typical of new chemicals, but also true for many existing chemicals), should include reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

**10.9.2.5.2** Well-substantiated human data showing a specific target organ toxic effect that can be reliably attributed to repeated or prolonged exposure to a chemical substance, would justify classification. Positive human data, regardless of probable dose, takes precedence over animal data. Thus, if a substance has not been classified because no specific target organ toxicity was observed at or below the proposed dose/concentration guidance value for animal testing, but subsequent human incident data become available showing a specific target organ systemic toxic effect, then the substance should be classified.

**10.9.2.5.3** A substance that has not been tested for specific target organ toxicity could be classified on the basis of data from a validated structure activity relationship and expert judgement-based extrapolation from a structural analogue that has previously been classified, together with support from other factors such as the formation of common significant metabolites.

**10.9.2.5.4** Saturated vapour concentration may be taken into account as an additional element for specific health and safety protection.



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### **10.9.3 Classification criteria for mixtures**

#### **10.9.3.1 General**

Mixtures are classified for specific target organ toxicity – repeated exposure by using the same criteria as for substances, or alternatively, as described in 10.9.3.2 to 10.9.3.4.

#### **10.9.3.2 Classification of mixtures when data are available for the complete mixture**

When reliable and good quality evidence from human experience or animal testing as described in the classification criteria for substances (see 10.9.2), is available for a mixture, then the mixture can be classified by weight of evidence evaluation of this data. Care should be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

#### **10.9.3.3 Classification of mixtures when data are not available for the complete mixture: Bridging principles**

##### **10.9.3.3.1 General**

Where the mixture itself has not been tested to determine its target organ toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data can be used in accordance with the bridging principles given in 10.9.3.3.2 to 10.9.3.3.7. This ensures that available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity of additional animal testing.

##### **10.9.3.3.2 Dilution**

If a mixture is diluted with a substance that has the same, or a lower, toxicity classification as the least toxic original ingredient and that is not expected to affect the toxicity of other ingredients, then the new mixture can be classified as equivalent to the original mixture.

##### **10.9.3.3.3 Batching**

The specific target organ effects toxicity – repeated exposure, of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by, or under the control of, the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity potential of the batch has changed. If the latter occurs, a new classification is necessary.

##### **10.9.3.3.4 Concentration of highly toxic mixtures**

In the case of a highly toxic mixture of category 1, where the concentration of a toxic ingredient is increased, such a concentrated mixture shall be classified in category 1 without additional testing.

##### **10.9.3.3.5 Interpolation within one toxicity category**

For three mixtures with identical ingredients, where mixture A and mixture B are in the same toxicity category, and mixture C has the same toxicologically active ingredients with concentrations intermediate to the concentrations of those ingredients in mixtures A and B, then mixture C is assumed to be in the same toxicity category as mixture A and mixture B.



#### **10.9.3.3.6 Substantially similar mixtures**

In the case of two mixtures (A + B) and (C + B) where

- a) the concentration of ingredient B is essentially the same in both mixtures,
- b) the concentration of ingredient A equals that of ingredient C,
- c) the toxicity data for toxicity for ingredient A and ingredient C are available and substantially equivalent, that is, they are in the same hazard category and are not expected to affect the toxicity of ingredient B, and
- d) mixture (A + B) has already been classified by testing, then mixture (C + B) can be assigned the same category. as that of mixture (A + B).

#### **10.9.3.3.7 Aerosols**

For oral and dermal toxicity, a mixture in aerosol form can be classified in the same hazard category as the tested non-aerosol form, provided that the added propellant does not affect the toxicity of the mixture on spraying. For inhalation toxicity, the classification of a mixture in aerosol form and that of the tested non-aerosol form should be considered separately.

#### **10.9.3.4 Classification of mixtures when data are available for all components or only for some components of the mixture**

**10.9.3.4.1** When no reliable evidence or test data are available on a mixture and the bridging principles (see 10.9.3.3.2 to 10.9.3.3.7) cannot be applied, classification of the mixture shall be based on the classification of the ingredient substances. In such a case, the mixture shall be classified as a target organ toxicant (specific organ specified), following single exposure, repeat exposure, or both, when at least one ingredient

- a) has been classified as a category 1 or a category 2 target organ toxicant, and
- b) is present at or above the appropriate cut-off values/concentration limits as given in table 51.

**10.9.3.4.2** The cut-off values/concentration limits and consequent classification shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

**10.9.3.4.3** Mixtures shall be classified for single- or repeated-dose (or both) toxicity independently.

**10.9.3.4.4** When toxicants affecting more than one organ system are combined, the potentiation or synergistic interactions shall be taken into account since certain substances cause target organ toxicity at concentrations less than 1 % when other ingredients in the mixture are known to potentiate its toxic effect.

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**Table 51 — Cut-off values/concentration limits of the ingredients of a mixture classified as a specific target organ toxicant – repeated exposure, that trigger classification of the mixture**

1	2	3
<b>Hazard category of the ingredient classified as a specific target organ systemic toxicant</b>	<b>Cut-off values/concentration limits of the ingredients of a mixture that triggers classification of a mixture as a target organ toxicant – repeated exposure</b>	
	%	
<b>Category 1</b>	<b>Category 1</b>	<b>Category 2</b>
	≥ 1,0 (see NOTE 1)	
	≥ 10 (see NOTE 2)	
<b>Category 2</b>		≥ 1,0 (see NOTE 3)
		≥ 10 (see NOTE 4)
<p>NOTE 1 If a category 1 target organ toxicant is present in the mixture at a concentration between 1,0 % and 10 %, an SDS is required for such a mixture. However, a warning on the label is optional.</p> <p>NOTE 2 If a category 1 target organ toxicant is present in the mixture at a concentration equal to or more than 10 %, an SDS is required for such a mixture as well as a warning on the label.</p> <p>NOTE 3 If a category 2 target organ toxicant is present in the mixture at a concentration between 1,0 % and 10 %, an SDS for such a mixture is required. However, a warning on the label is optional.</p> <p>NOTE 4 If a category 2 target organ toxicant is present in the mixture at a concentration of equal to or more than 10 %, an SDS is required for such a mixture as well as a warning on the label.</p>		

### 10.9.4 Hazard communication

The label elements for substances and mixtures classified as specific target organ toxicants after repeated exposure are given in table 52. See also:

- a) clause 6 for general and specific consideration concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 52 — Label elements for specific target organ toxicity – repeated exposure**

1	2	3
	<b>Category 1</b>	<b>Category 2</b>
<b>Symbol</b>	Health hazard	Health hazard
<b>Signal word</b>	Danger	Warning
<b>Hazard statement</b>	Causes damage to organs (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard )	May cause damage to organs (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

## **10.10 Aspiration hazards**

### **10.10.1 General**

**10.10.1.1** A substance or a mixture that poses an aspiration hazard (see 3.1.6) causes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.

**10.10.1.2** Aspiration is initiated at the moment of inhalation. In the time required to take one breath, the inhaled material lodges at the crossroad of the upper respiratory and digestive tracts in the laryngopharyngeal region.

**10.10.1.3** Aspiration of a substance or a mixture can occur if it is vomited after ingestion. This has consequences for labelling, particularly where, due to acute toxicity, a recommendation might be considered to induce vomiting after ingestion. Therefore, if the substance or mixture also presents an aspiration toxicity hazard, the recommendation to induce vomiting needs to be modified.

**10.10.1.4** Some hydrocarbons (petroleum distillates, kerosene) and certain chlorinated hydrocarbons pose an aspiration hazard in humans. However, primary alcohols and ketones pose an aspiration hazard only in animal studies (see also 10.10.1.5).

**10.10.1.5** While the methodology for the determination of aspiration hazard by animal testing has been utilized, it has not been standardized. Therefore, positive experimental evidence with test animals only serves as a guide to possible aspiration toxicity in humans and particular care should be taken in evaluating animal data for aspiration hazards.

**10.10.1.6** The classification criteria for aspiration toxicity refer to kinematic viscosity. The following formula provides the conversion between dynamic and kinematic viscosity:

$$V = \frac{N}{d}$$

where

$V$  is the kinematic viscosity, in millimetres squared per second;

$N$  is the dynamic viscosity, in millipascal second;

$d$  is the density, in gram per cubic millimetre.

### **10.10.2 Aerosol and mist products**

Aerosol and mist products are dispensed in containers such as self-pressurized containers, pressurized trigger sprayers and pump sprayers. The key to the classification of aerosol and mist products is whether a pool of product is formed in the mouth which might be aspirated. If a fine aerosol or mist is dispensed from the pressurized container, a pool might not be formed. On the other hand, if a pressurized container dispenses the product in a stream, a pool might be formed that could be aspirated. Usually, the mist produced by trigger and pump sprayers is coarse and therefore a pool might be formed that could be aspirated. When the pump mechanism is removed from a container and the contents are available to be swallowed, then the classification of the product shall be considered.

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### 10.10.3 Classification criteria for substances

**Table 53 — Hazard categories for aspiration toxicity**

1	2	3
Hazard category	Adverse effect	Criteria
1	Chemicals known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazards.	a) Reliable and good quality human evidence (see NOTE 1); or b) hydrocarbons that have a kinematic viscosity of 20,5 mm <sup>2</sup> /s or less at 40 °C.
2	Chemicals that cause concern owing to the presumption that they cause human aspiration toxicity hazards.	a) Existing animal studies and expert judgment that take into account surface tension, water solubility, boiling point, and volatility; or b) substances, other than those classified in category 1, that have a kinematic viscosity of 14 mm <sup>2</sup> /s or less at 40 °C (see NOTE 2).
NOTE 1 Examples of substances included in category 1 are certain hydrocarbons, turpentine and pine oil.		
NOTE 2 Examples of substances included in category 2 are n-primary alcohols with a chain length of at least three carbon atoms but not more than thirteen, isobutyl alcohol, and ketones that contain not more than thirteen carbon atoms.		

### 10.10.4 Classification criteria for mixtures

#### 10.10.4.1 Classification when data are available for the complete mixture

A mixture is classified in category 1 based on reliable and good quality human evidence.

#### 10.10.4.2 Classification of mixtures when data are not available for the complete mixture: Bridging principles

##### 10.10.4.2.1 General

Where the mixture itself has not been tested to determine its aspiration toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterize the hazard of the mixture, these data can be used in accordance with the bridging principles given in 10.10.4.2.2 to 10.10.4.2.6. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity of additional animal testing.

##### 10.10.4.2.2 Dilution

If a mixture is diluted with a substance that does not pose an aspiration toxicity hazard, and that is not expected to affect the aspiration toxicity of other ingredients or the mixture, then the new mixture can be classified as equivalent to the original mixture, provided that the concentration of aspiration toxicant(s) does not drop below 10 %.

#### **10.10.4.2.3 Batching**

The aspiration toxicity of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by, or under the control of, the same manufacturer unless there is reason to believe there is significant variation such that the aspiration toxicity (reflected by viscosity or concentration), of the batch has changed. If the latter occurs, a new classification is necessary.

#### **10.10.4.2.4 Concentration of hazard category 1 mixtures**

If a mixture is classified as an aspiration toxicant of category 1 and the concentration of the category 1 ingredient(s) is increased, the new mixture shall be classified in category 1 without additional testing.

#### **10.10.4.2.5 Interpolation within one hazard category**

For three mixtures with identical ingredients, where mixture A and mixture B are in the same hazard category, and mixture C contains the same toxicologically active ingredients with concentrations intermediate to the concentrations of those ingredients in mixtures A and B, then mixture C is classified in the same hazard category as mixture A and mixture B.

#### **10.10.4.2.6 Substantially similar mixtures**

In the case of two mixtures (A + B) and (C + B) where

- a) the concentration of ingredient B is essentially the same in both mixtures,
- b) the concentration of ingredient A equals that of ingredient C,
- c) the aspiration toxicity of ingredient A and ingredient C are substantially equivalent, that is, they are in the same hazard category and are not expected to affect the aspiration toxicity of ingredient B, and
- d) mixture (A+B) has already been classified based on the criteria given in table 52,

then mixture (C + B) can be assigned the same hazard category as that of mixture (A + B).

#### **10.10.4.3 Classification of mixtures when data are available for all components or only for some components of the mixture**

##### **10.10.4.3.1 Hazard category 1**

**10.10.4.3.1.1** A mixture that contains a total of 10 % or more of a substance or substances classified as (an) aspiration toxicant(s) of category 1, and that has a kinematic viscosity of 20,5 mm<sup>2</sup>/s or less at 40 °C, shall be classified in category 1.

**10.10.4.3.1.2** If a mixture separates into two or more distinct layers and one of the layers contains 10 % or more of a substance or substances classified in category 1 and has a kinematic viscosity of 20,5 mm<sup>2</sup>/s or less at 40 °C, then the entire mixture shall be classified in category 1.

##### **10.10.4.3.2 Hazard category 2**

**10.10.4.3.2.1** A mixture that contains a total of 10 % or more of a substance or substances classified in category 2, and has a kinematic viscosity of 14 mm<sup>2</sup>/s or less at 40 °C, shall be classified in category 2.

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**10.10.4.3.2.2** Expert judgment taking into account surface tension, water solubility, boiling point and volatility is critical for the classification of a mixture in category 2 and especially when category 2 substances are mixed with water.

**10.10.4.3.2.3** If a mixture separates into two or more distinct layers and one of the layers contains 10 % or more of a substance or substances classified in category 2 and has a kinematic viscosity of 14 mm<sup>2</sup>/s or less at 40 °C, then the entire mixture shall be classified in category 2.

### 10.10.5 Hazard communication

The label elements for substances and mixtures that are classified as hazardous by aspiration are given in table 54. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 54 — Label elements for substances and mixtures that pose an aspiration hazard**

1	2	3
	<b>Hazard category 1</b>	<b>Hazard category 2</b>
<b>Symbol</b>	Health hazard	Health hazard
<b>Signal word</b>	Danger	Warning
<b>Hazard statement</b>	May be fatal if swallowed and enters airways	May be harmful if swallowed and enters airways

## 11 Hazards to the aquatic environment

### 11.1 General

**11.1.1** The primary objective for the classification of substances and mixtures as hazardous to the environment is to alert the user to the hazards these substances and mixtures present to ecosystems. Although the present criteria refer by and large to aquatic ecosystems, it is known that certain substances and mixtures simultaneously, or alternatively, affect other ecosystems that range from soil microflora to primates.

**11.1.2** The basic elements used for the classification of substances and mixtures as hazardous to the aquatic environment are:

- a) acute aquatic toxicity (see 11.1.4);
- b) bioaccumulation (see 3.1.8 and 11.1.5);
- c) degradation (abiotic or biotic) for organic chemicals (3.1.1, 3.1.12, 3.1.23, 11.1.6 and 11.1.7); and
- d) chronic aquatic toxicity (see 3.1.16 and 11.1.8).

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**11.1.3** The toxicity data on freshwater species and marine species are considered as equivalent data for the classification of substances and mixtures as hazardous to the environment. The relevant test methods set out in the OECD Test Guidelines (see annex J) or any other internationally recognized test method, may be used for the classification of a substance or mixture and in accordance with the principles of Good Laboratory Practices (GLP). Where such data are not available classification should be based on the best available data.

**11.1.4** The acute aquatic toxicity is determined by exposing:

- a) a fish population for a period of 96 h ( $LC_{50}$ ) (OECD 203);
- b) a crustacea (daphnia, water flea) species for a period of 48 h ( $EC_{50}$ ) (OECD 202); or
- c) alga species or other aquatic plants for a period of 72 h or 96 h ( $ErC_{50}$ ) (OECD 201).

NOTE These species are considered as surrogate for all aquatic organisms and data on other species, such as Lemna, may also be considered if the test methodology is suitable.

**11.1.5** The potential for bioaccumulation (see 3.1.8) is determined by using the octanol-water partition coefficient (see 3.1.59), usually reported as a log  $K_{ow}$  and determined by OECD 107 or OECD 117. While this represents a potential to bioaccumulate, a bioconcentration factor (BCF) (see 3.1.11), determined experimentally in accordance with OECD 305, provides a better measure and should be used in preference when available.

**11.1.6** Ready environmental degradation may be biotic or abiotic, for example hydrolysis. Biodegradation in fresh water can be determined by means of OECD 301 (A - F). A pass level in these tests is considered as indicative of rapid degradation in most environments. However, OECD 306 is more suitable for marine environments. Where such data are not available, a substance or mixture is considered readily degradable if the ratio  $BOD_5/COD$  is greater than 0,5.

NOTE The subscript 5 indicates that a BOD test was run over a five-day period.

**11.1.7** Abiotic degradation such as hydrolysis, primary degradation, both abiotic and biotic, degradation in non-aquatic media and proven rapid degradation in the environment should all be considered in defining rapid degradability. Special guidance on data interpretation is provided in annex F and annex G.

**11.1.8** Chronic aquatic toxicity (see 3.1.16) data are less available than acute aquatic toxicity (see 3.1.3) data and the range of testing procedures are less standardized. However, data generated according to OECD 210, OECD 211 and OECD 201, as well as other internationally recognized tests, are acceptable (see also G.3.3.2).

## 11.2 Classification criteria for substances

### 11.2.1 General

**11.2.1.1** Substances hazardous to the aquatic environment can be allocated to three hazard categories of acute toxicity (see table 55) and four hazard categories of chronic toxicity (see table 56). The hazard categories of acute toxicity and the hazard categories of chronic toxicity are applied independently. The classification of a substance in hazard categories 1 to 3 of acute toxicity is based on acute toxicity data only ( $EC_{50}$  or  $LC_{50}$ ). The classification of a substance in hazard categories 1 to 4 of chronic toxicity combines two types of information, that is, acute toxicity data and environmental fate data (degradability and bioaccumulation data).

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**11.2.1.2** The assignment of mixtures to hazard category 1 up to hazard category 4 of chronic toxicity is derived from degradation and bioaccumulation tests on components of the mixtures.

**11.2.1.3** Substances classified in accordance with the criteria given in table 55 and table 56 are regarded as hazardous to the aquatic environment. See table 57 for the summarised classification scheme.

**Table 55 — Hazard categories of acute toxicity for substances hazardous to the aquatic environment**

1	2
Hazard category of acute toxicity	Classification criteria
1	96 h $LC_{50}$ (for fish) $\leq 1\text{ mg/L}$ 48 h $EC_{50}$ (for crustacea) $\leq 1\text{ mg/L}$ 72 h or 96 h $ErC_{50}$ (for algae or other aquatic plants) $\leq 1\text{ mg/L}$
2	96 h $LC_{50}$ (for fish) $> 1$ to $\leq 10\text{ mg/L}$ and/or 48 h $EC_{50}$ (for crustacea) $> 1$ to $\leq 10\text{ mg/L}$ and/or 72 h or 96 h $ErC_{50}$ (for algae or other aquatic plants) $> 1$ to $\leq 10\text{ mg/L}$
3	96 h $LC_{50}$ (for fish) $> 10$ – $\leq 100\text{ mg/L}$ and/or 48 h $EC_{50}$ (for crustacea) $> 10$ – $\leq 100\text{ mg/L}$ and/or 72 h or 96 h $ErC_{50}$ (for algae or other aquatic plants) $> 10$ – $\leq 100\text{ mg/L}$

**Table 56 — Hazard categories of chronic toxicity for substances hazardous to the aquatic environment**

1	2
Hazard category of chronic toxicity	Classification criteria
1	a) 96 h $LC_{50}$ (for fish) $\leq 1\text{ mg/L}$ ; and/or b) 48 h $EC_{50}$ (for crustacea) $\leq 1\text{ mg/L}$ ; and/or c) 72 h or 96 h $ErC_{50}$ (for algae or other aquatic plants) $\leq 1\text{ mg/L}$ ; and d) the substance is not rapidly degradable; and/or e) the $\log K_{ow}$ $\geq 4$ (unless the experimentally determined BCF $< 500$ ).
2	a) 96 h $LC_{50}$ (for fish) $> 1$ to $\leq 10\text{ mg/L}$ and/or b) 48 h $EC_{50}$ (for crustacea) $> 1$ to $\leq 10\text{ mg/L}$ ; and/or c) 72 h or 96 h $ErC_{50}$ (for algae or other aquatic plants) $> 1$ to $\leq 10\text{ mg/L}$ ; and d) the substance is not rapidly degradable; and/or e) the $\log K_{ow}$ $\geq 4$ (unless the experimentally determined BCF $< 500$ ); and f) unless the chronic NOECs are $> 1\text{ mg/L}$



**Table 56** (concluded)

1	2
Hazard category of chronic toxicity	Classification criteria
3	<p>a) 96 h <math>LC_{50}</math> (for fish) &gt; 10 to ≤ 100 mg/L; and/or</p> <p>b) 48 h <math>EC_{50}</math> (for crustacea) &gt; 10 to ≤ 100 mg/L; and/or</p> <p>c) 72 h or 96 h <math>ErC_{50}</math> (for algae or other aquatic plants) &gt; 10 to ≤ 100 mg/L; and</p> <p>d) the substance is not rapidly degradable; and/or</p> <p>e) the log <math>K_{ow}</math> ≥ 4 (unless the experimentally determined BCF &lt; 500); and</p> <p>f) unless the chronic NOECs are &gt; 1 mg/L</p>
4	<p>Poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility, that are not rapidly degradable and have a <math>\log K_{ow} \geq 4</math>, indicating a potential to bioaccumulate are to be classified in this category, unless other scientific evidence shows classification to be unnecessary. Such evidence would include an experimentally determined BCF &lt; 500, or a chronic toxicity NOECs &gt;1 mg/L, or evidence of rapid degradation in the environment.</p>

**11.2.1.4** The intrinsic hazard to aquatic organisms is represented by both the acute and the chronic toxicity of a substance. A distinction is made between the acute hazards and the chronic hazards of a substance and therefore separate hazard categories are defined for both properties representing a gradation in the level of hazards identified. The lowest of the available toxicity values shall be used for the allocation of (a) hazard category(ies). There might be circumstances, however, when a weight of evidence approach needs to be used. Acute toxicity forms the basis for classification of substances as hazardous to the environment since the data are readily available and the test methods are standardized (see annex J).

**11.2.1.5** Acute toxicity represents a key property in defining the hazard where transport of large quantities of a substance might give rise to short-term dangers arising from accidents or major spillages.

**11.2.1.6** A packaged substance that has an acute toxicity ( $L(E)C_{50}$ ) equal to or less than 1 mg/L can be considered as hazardous to the environment. At toxicity levels above 1 mg/L, the short-term toxicity does not reflect the hazards that arise from low concentrations causing effects over a longer time scale. As chronic toxicity data are not available for many substances, it is necessary to use available acute toxicity data to estimate chronic toxicity. The intrinsic properties of a lack of rapid degradability or a potential to bioconcentrate (or both) in combination with acute toxicity can be used to assign a substance to a chronic hazard category. Classification of a substance in a chronic hazard category is not necessary if the NOECs is greater than 1 mg/L. Likewise, a chronic toxicity  $L(E)C_{50}$  greater than 100 mg/L is considered as insufficient to warrant classification.

**11.2.1.7** The assignment of a chronic hazard category is based on acute toxicity data in combination with a lack of rapid degradation or a potential to bioaccumulate (or both).

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**Table 57 — Classification scheme for substances hazardous to the aquatic environment**

1	2	3	4	5	6
Classification criterion elements				Hazard categories	
Toxicity		Degradability <sup>e</sup>	Bioaccumulation <sup>f</sup>		
Acute <sup>a, b</sup>	Chronic <sup>c, d</sup>			Acute	Chronic
<b>Box 1</b>  Value ≤ 1mg/L		<b>Box 5</b>  Lack of rapid degradability	<b>Box 6</b>  BCF ≥ 500 or, if absent <i>log K<sub>ow</sub></i> ≥ 4	<b>Category 1</b>  Box 1	<b>Category 1</b>  Boxes 1+5+6 Boxes 1+5 Boxes 1+6
<b>Box 2</b>  1 < value ≤ 10 mg/L				<b>Category 2</b>  Box 2	<b>Category 2</b>  Boxes 2+5+6 Boxes 2+5 Boxes 2+6 Unless Box 7
<b>Box 3</b>  10 < value ≤ 100 mg/L				<b>Category 3</b>  Box 3	<b>Category 3</b>  Boxes 3+5+6 Boxes 3+5 Boxes 3+6 Unless Box 7
<b>Box 4</b>  No acute toxicity <sup>g</sup>	<b>Box 7</b>  Value > 1 mg/L				<b>Category 4</b>  Boxes 4+5+6 Unless Box 7

<sup>a</sup> The acute toxicity band is based on  $L(E)C_{50}$  values in mg/L for fish, crustacea or algae (or both), or other aquatic plants (or QSAR estimation if no experimental data are available).

<sup>b</sup> Where the algal toxicity  $ErC_{50}$  ( $EC_{50}$  (growth rate)) falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration should be given to whether this toxicity is representative of the toxicity to aquatic plants. Where it can be shown that this is not the case, professional judgement should be used in deciding if classification should be applied. Classification should be based on the  $ErC_{50}$ . In circumstances where the basis of the  $EC_{50}$  is not specified and no  $ErC_{50}$  is recorded, classification should be based on the lowest  $EC_{50}$  available.

<sup>c</sup> The chronic toxicity band is based on NOEC values in mg/L for fish or crustacea, or other recognised measures for long-term toxicity.

<sup>d</sup> It is the intention that the system be further developed to include chronic toxicity data.

<sup>e</sup> Lack of rapid degradability is based on either a lack of ready biodegradability or other evidence of lack of rapid degradation.

<sup>f</sup> The potential for bioaccumulation is based on an experimentally derived  $BCF \geq 500$  or if absent, a  $\log K_{ow} \geq 4$ , provided that  $\log K_{ow}$  is an appropriate descriptor for the bioaccumulation potential of the substance. Experimental values of  $\log K_{ow}$  take precedence over estimated values, and experimental BCF values take precedence over  $\log K_{ow}$  values.

<sup>g</sup> “No acute toxicity” means that the  $L(E)C_{50}$  is higher than the water solubility. “No acute toxicity” also applies to substances with a water solubility < 1 mg/L) and where there is evidence that the acute toxicity test would not provide a true measure of the intrinsic toxicity.

### **11.2.2 Aquatic toxicity**

**11.2.2.1** Fish, crustacea and algae are tested as surrogate species covering a range of trophic levels and taxa in accordance with standardized test methods (see annex J). Data on other organisms could also be taken into account, provided that they represent equivalent species and test endpoints. The algal growth inhibition test is a chronic test but the  $EC_{50}$  is treated as an acute value for classification purposes, normally based on growth rate inhibition. If only the  $EC_{50}$  based on the reduction in biomass is available, or if is not indicated which  $EC_{50}$  is reported, this value may be used in the same way.

**11.2.2.2** Aquatic toxicity testing involves the dissolution of the test substance in the water media used and the maintenance of a stable bioavailable exposure concentration over the course of the test.

### **11.2.3 Bioaccumulation**

The bioaccumulation of substances within aquatic organisms gives rise to toxic effects over longer time-scales even when actual water concentrations are low. The potential to bioaccumulate is determined by the partitioning between n-octanol and water. The relationship between the partition coefficient of an organic substance and its bioconcentration as measured by the BCF in fish, has considerable scientific literature support. A cut-off value of  $\log K_{ow} \geq 4$  is intended to identify only those substances with a real potential to bioconcentrate. It should therefore be recognized that  $\log K_{ow}$  is only a surrogate for a measured BCF, and such a measured BCF value shall always take precedence. A BCF in fish of less than 500 is indicative of a low level of bioconcentration.

### **11.2.4 Rapid degradability**

**11.2.4.1** A substance is considered rapidly degradable in the aquatic environment if the following criteria are satisfied:

a) If, in a 28 d biodegradation study, the following levels of degradation are achieved:

- 1) **tests based on dissolved organic carbon:** 70 %; and
- 2) **tests based on oxygen depletion or carbon dioxide generation:** 60 % of the theoretical maxima.

These levels of biodegradation shall be achieved within 10 d of the start of degradation, which is taken as the time when 10 % of the substance has been degraded.

b) If the ratio  $BOD_5/COD$  is greater than or equal to 0,5 in those cases where only BOD and COD data are available.

NOTE The subscript 5 indicates that the BOD test was run over a five-day period.

c) If other convincing scientific evidence is available to demonstrate that the substance can be degraded biotically or abiotically (or both) in the aquatic environment to a level exceeding 70 % within a 28 d period.

**11.2.4.2** Rapid degradable substances are quickly removed from the aquatic environment. While effects can occur, particularly in the event of a spillage or an accident, they will be localised and of short duration. In the absence of rapid degradation in the aquatic environment, a substance has the potential to exert toxicity over a wide temporal and spatial scale. Biodegradation screening tests are used to determine whether a substance is "readily biodegradable". Thus a substance that passes the screening test is likely to biodegrade "rapidly" in the aquatic environment, and is unlikely to be persistent. However, a fail in the screening test does not necessarily mean that a substance will not

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degrade rapidly in the environment. Degradation data are available in the form of degradation half-lives and can also be used in defining rapid degradation (see G.4). Some tests measure the ultimate biodegradation of the substance, that is, full mineralization is achieved. Primary biodegradation does not normally qualify in the assessment of rapid degradability, unless it can be demonstrated that the degradation products do not fulfil the criteria for classification as hazardous to the aquatic environment.

**11.2.4.3** Environmental degradation could be biotic or abiotic, for example, hydrolysis. Hydrolysis should be taken into account if the hydrolysis products of a substance do not fulfil the criteria for classification as hazardous to the aquatic environment. Other evidence of rapid degradation in the environment may also be considered and may be of particular importance where the substances are inhibitory to microbial activity at the concentration levels used in standard testing (see annex J).

### **11.2.5 Inorganic compounds and metals**

**11.2.5.1** The concept of degradability as applied to organic compounds has limited or no meaning for inorganic compounds and metals as they can be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Likewise, the use of bioaccumulation data for inorganic substances should be treated with care (see also G.6.1.7).

**11.2.5.2** Poorly soluble inorganic compounds and metals (see G.6.1.4) can be acutely or chronically toxic in the aquatic environment depending on the intrinsic toxicity of the bioavailable inorganic species and the rate and amount of these species that enter solution (see annex H for a test protocol).

### **11.2.6 Hazard category 4 of chronic toxicity**

Hazard category 4 of chronic toxicity has been introduced in the classification system as a “safety net” when the available data do not allow for classification under the formal criteria but there are nevertheless some grounds for concern. Where no toxicity has been demonstrated for poorly water soluble organic substances, classification might still be relevant if the substance is not rapidly degraded and has a potential to bioaccumulate. It is considered that for poorly soluble substances, the toxicity might not have been adequately assessed in the short-term test due to the low exposure levels and potentially slow uptake into the organism. The need for classification can be negated by demonstrating the absence of chronic (long-term) effects (NOECs), that is, an NOEC greater than the water solubility of the substance or 1 mg/L, or rapid degradation in the environment.

### **11.2.7 Quantitative activity relationships (QSARs)**

Experimentally derived test data are preferred for the classification of a substance as hazardous to the aquatic environment. However, when no experimental data are available, validated quantitative structure activity relationships (QSARs) for aquatic toxicity and  $\log K_{ow}$  shall be used. Such validated QSARs can be used without modification to the agreed criteria, provided that they are restricted to chemicals for which their mode of action and applicability are well characterized. Reliable calculated toxicity and  $\log K_{ow}$  values are valuable in the “safety net” context (see also 11.1.5).

NOTE QSARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation.

## 11.3 Classification criteria for mixtures

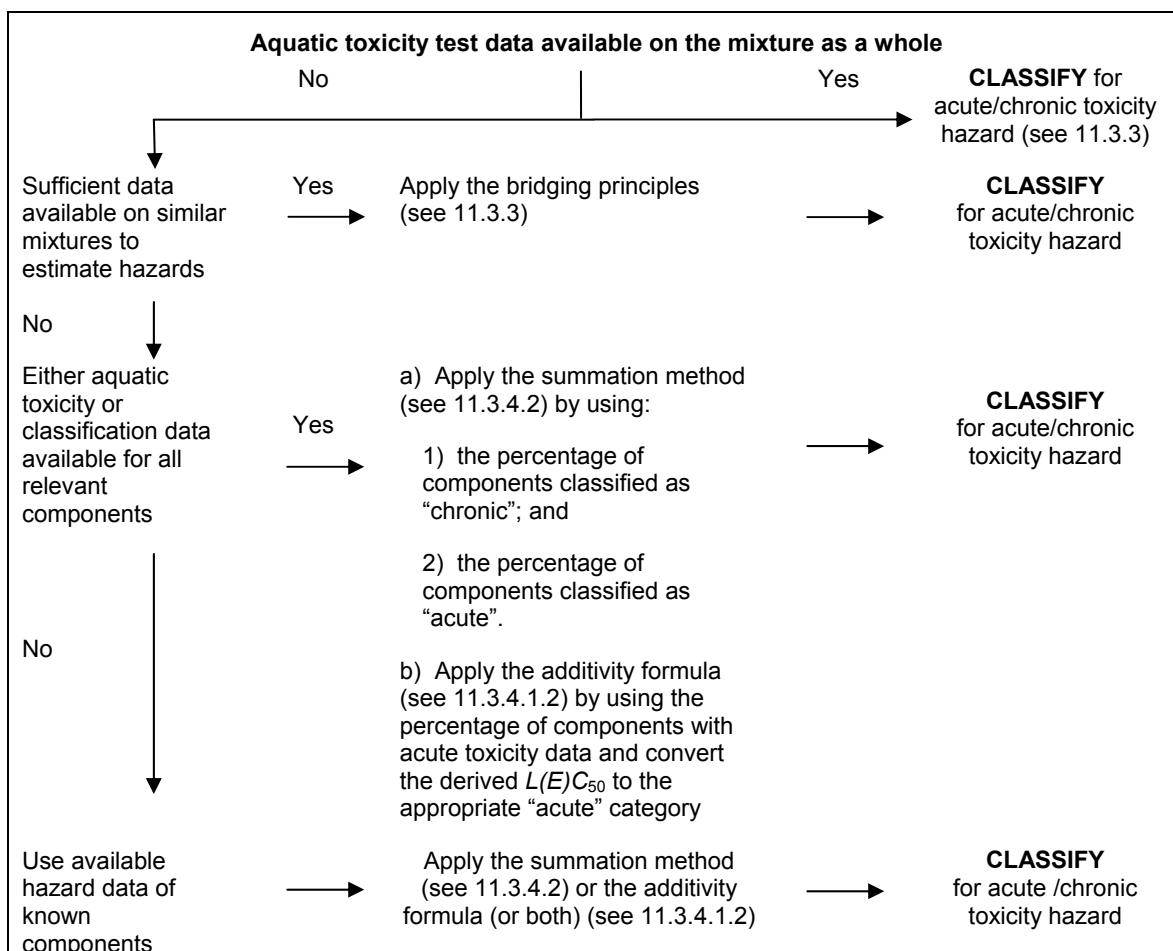
### 11.3.1 General

**11.3.1.1** Mixtures are assigned to the same hazard categories as for substances (see table 55 and table 56).

**11.3.1.2** The “relevant components” of a mixture are those components present at a concentration  $\geq 1\%$ , by mass, unless there is a presumption (for example, in the case of highly toxic components) that a component at a concentration less than  $1\%$ , by mass, is still relevant for classification of the mixture as hazardous to the aquatic environment.

**11.3.1.3** The approach for the classification of mixtures as hazardous to the aquatic environment is tiered and is dependent upon the type of information available for the mixture itself and for its components (see flow chart 4). Elements of the tiered approach include:

- a) classification based on tested mixtures;
- b) classification based on bridging principles (see 11.3.3), and
- c) the use of “summation of classified components” (see 11.3.4.2) or an “additivity formula” (or both).



**Flow chart 4 — Tiered approach to classification of mixtures for acute and chronic aquatic environmental hazards**

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### **11.3.2 Classification of mixtures when data are available for the complete mixture**

#### **11.3.2.1 General**

**11.3.2.1.1** Aquatic toxicity testing on a mixture as a whole can only be done for acute toxicity. The classification shall be based on the data for fish, crustacea and algae. Classification of mixtures as a whole is not possible for chronic categories since both toxicity data and environmental fate data are needed, and there are no degradability and bioaccumulation data available for mixtures as a whole. Furthermore, it is not possible to apply the criteria for chronic classification because the data from degradability and bioaccumulation tests of mixtures cannot be interpreted; they are meaningful only for single substances.

**11.3.2.1.2** When acute toxicity test data ( $LC_{50}$  or  $EC_{50}$ ) are available for the mixture as a whole this data as well as information with respect to the classification of the components for chronic toxicity shall be used to complete the classification for tested mixtures. Chronic (long-term) toxicity data (NOEC) should also be used if available.

#### **11.3.2.2 Classification**

**11.3.2.2.1** A mixture with an experimental  $L(E)C_{50}$  ( $LC_{50}$  or  $EC_{50}$ )  $\geq 100$  mg/L and an experimental NOEC  $\leq 1,0$  mg/L, or unknown, can be classified as:

- a) hazard category 1, 2, or 3 of acute toxicity; or
- b) hazard category 1, 2, 3 or 4 of chronic toxicity by means of the summation method (see 11.3.4.2); or
- c) no need for chronic classification.

**11.3.2.2.2** A mixture with an experimental  $L(E)C_{50} < 100$  mg/L and an experimental NOEC  $> 1,0$  mg/L can be classified as follows:

- a) hazard category 1, 2 or 3 of acute toxicity; or
- b) hazard category 1 of chronic toxicity by means of the summation method (see 11.3.4.2).

NOTE If the mixture is not classified as hazard category 1 of chronic toxicity, then there is no need for chronic classification.

**11.3.2.2.3** A mixture with an experimental  $L(E)C_{50} > 100$  mg/L, or above the water solubility, and an experimental NOEC  $\leq 1,0$  mg/L, or unknown, can be classified as follows:

- a) no need to classify for acute toxicity; or
- b) hazard category 4 of chronic toxicity by means of the summation method (see 11.3.4.2); or
- c) no need to classify for chronic toxicity.

**11.3.2.2.4** A mixture with an experimental  $L(E)C_{50} > 100$  mg/L, or above the water solubility, and an NOEC  $> 1,0$  mg/L need not be classified for either acute toxicity or chronic toxicity to the aquatic environment.

### **11.3.3 Classification of mixtures when data are not available for the complete mixture: Bridging principles**

#### **11.3.3.1 General**

Where the mixture itself has not been tested to determine its aquatic environmental hazard, but there are sufficient data on the individual components and similar tested mixtures to adequately characterize the hazards of the mixture, these data can be used in accordance with the bridging principles given in 11.3.3.2 to 11.3.3.6. This ensures that the available data are used to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional animal testing.

#### **11.3.3.2 Dilution**

**11.3.3.2.1** If a mixture is formed by dilution with another classified substance or mixture that has an equivalent, or lower, aquatic hazard classification than the least toxic original component and that is not expected to affect the aquatic hazards of other components, then the new mixture can be classified as equivalent to the original substance or mixture.

**11.3.3.2.2** If a mixture is formed by the dilution of a classified substance or mixture with water, or with a non-toxic material, then the toxicity of the new mixture can be calculated from the toxicity of the original substance or mixture.

#### **11.3.3.3 Batching**

The aquatic hazard classification of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by, or under the control of, the same manufacturer, unless there is reason to believe there is significant variation such that the aquatic hazard classification of the batch has changed. If the latter occurs, a new classification is necessary.

#### **11.3.3.4 Concentration of severely hazardous mixtures**

If a mixture, classified in category 1 of acute toxicity or in hazard category 1 of chronic toxicity (or both), are further concentrated, the more concentrated mixture shall remain classified in category 1 as for the mixture without additional testing.

#### **11.3.3.5 Interpolation within one toxicity category**

Where two mixtures, mixture A and mixture B are classified in the same hazard category and another mixture, mixture C, is prepared with toxicological active components at concentrations intermediate to those of mixture A and mixture B, then mixture C is assumed to be in the same hazard category as mixture A and mixture B.

NOTE The identity of the components are the same in all three mixtures.

#### **11.3.3.6 Substantially similar mixtures**

In the case of two mixtures (A + B) and (C + B) where

- a) the concentration of component B is the same in both mixtures,
- b) the concentration of component A equals that of component C,
- c) the classification of component A and component C are available and are the same, that is, they are in the same hazard category and are not expected to affect the aquatic toxicity of B, and



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d) mixture (A + B) has already been classified by testing,

then there is no need to test mixture (C + B) and both mixtures would be classified in the same category.

### **11.3.4 Classification of mixtures when data are available for all components or only for some components of the mixture**

#### **11.3.4.1 General**

**11.3.4.1.1** The classification of a mixture is based on summation of the classification of its components. Therefore, the percentage of components classified as “acute” or “chronic” feeds straight into the summation method (see 11.3.4.2).

**11.3.4.1.2** A mixture can be made up of a combination of components classified in hazard categories 1, 2, or 3 of acute toxicity or in hazard categories 1, 2, 3 or 4 of chronic toxicity (or both), and components for which test data are available. When toxicity data are available for more than one component of the mixture, the combined toxicity of the components can be calculated by means of the additivity formula given below. The calculated toxicity is then used to assign an acute hazard category to that portion of the mixture and can subsequently be used in the application of the summation method.

$$\frac{\sum C_i}{L(E)C_{50m}} = \sum \frac{C_i}{L(E)C_{50i}}$$

where

$C_i$  is the concentration of component “i”, in percentage by mass;

$L(E)C_{50i}$  is the  $LC_{50}$  or  $EC_{50}$  for component “i”, in milligram per litre;

$n$  is the number of components, and “i” is running from 1 to  $n$ ;

$L(E)C_{50m}$  is the  $L(E) C_{50}$  of the part of the mixture with test data.

**11.3.4.1.3** When applying the additivity formula for part of a mixture, the toxicity of this part of the mixture shall be calculated by using the toxicity values for each substance that relate to the same species (fish, daphnia or algae) and then using the highest toxicity (lowest value) obtained, that is, the most sensitive of the three species. However, when toxicity data for each component are not available in the same species, the toxicity value of each component should be selected in the same manner that toxicity values are selected for the classification of substances, that is, the higher toxicity (from the most sensitive test organism) should be used. The calculated acute toxicity can then be used to classify this part of the mixture in hazard category 1, 2 or 3 of acute toxicity by using the same criteria as described for substances (see 11.2).

**11.3.4.1.4** If a mixture is classified by more than one method, the results of the method yielding the more conservative result should be used.



#### **11.3.4.2 Summation method**

**11.3.4.2.1** The underlying toxicity criteria of substances classified as hazard category 1 to hazard category 3 for acute toxicity or chronic toxicity (or both), differ by a factor 10 in moving from one hazard category to another (see table 58 and table 59). Substances classified in a high toxicity band could thus contribute to the classification of a mixture in a lower toxicity band. Therefore, the total contribution of all substances classified as hazard category 1 to hazard category 3 of acute toxicity or chronic toxicity (or both) needs to be considered.

**11.3.4.2.2** When a mixture contains components classified as hazard category 1 of acute toxicity, attention should be paid to the fact that such components with an  $LC_{50}$ ,  $EC_{50}$  and  $ErC_{50}$  well below 1 mg/L, even at a low concentration, could still contribute to the toxicity of the mixture. Pesticide formulations often contain active ingredients of high aquatic toxicity together with substances of high acute toxicity, for example organometallic compounds. For these types of mixtures the normal cut-off values/concentration limits could lead to an “underclassification” of the mixture. Therefore, multiplication factors should be applied to account for highly toxic components (see 11.3.4.3.4).

#### **11.3.4.3 Classification procedure**

##### **11.3.4.3.1 General**

In general, a more severe classification for a mixture overrides a less severe classification, for example, a hazard category 1 chronic classification overrides a hazard category 2 chronic classification. As a consequence, the classification procedure is completed when the result of the classification is hazard category 1 of chronic toxicity. A more severe classification than hazard category 1 chronic toxicity is not possible and therefore no further classification procedure is necessary.

##### **11.3.4.3.2 Classification for acute toxicity (hazard category 1 to hazard category 3)**

**11.3.4.3.2.1** All the components of a mixture classified in hazard category 1 of acute toxicity should be considered for the classification of the mixture. If the result of the calculation (see 11.3.4.1.2) shows a classification in hazard category 1 of acute toxicity for the mixture, no further classification is necessary.

**11.3.4.3.2.2** In cases where a mixture is not classified in hazard category 1 of acute toxicity, classification of the mixture in hazard category 2 of acute toxicity should be considered. A mixture is classified in hazard category 2 of acute toxicity if ten times the sum of all components classified in hazard category 1 of acute toxicity plus the sum of all components classified in hazard category 2 of acute toxicity is greater than 25 % (see table 58). If the result of the calculation (see 11.3.4.1.2) shows a classification in hazard category 2 of acute toxicity for the mixture, no further classification is necessary.

**11.3.4.3.2.3** In cases where a mixture is not classified in either hazard category 1 or hazard category 2 of acute toxicity, classification of the mixture in hazard category 3 of acute toxicity should be considered. A mixture is classified in hazard category 3 of acute toxicity if 100 times the sum of all components classified in hazard category 1 of acute toxicity, plus 10 times the sum of all components classified in hazard category 2 of acute toxicity, plus the sum of all components classified in hazard category 3 of acute toxicity is greater than 25 % (see table 58).

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**Table 58 — Classification of mixtures for acute hazards to the aquatic environment, based on the summation of classified components**

1	2
Sum of components classified as:	Acute hazard category of the mixture
Acute 1 $\times M^a$ > 25 %	1
$(M \times 10 \times \text{Acute 1}) + \text{Acute 2}$ > 25 %	2
$(M \times 100 \times \text{Acute 1}) + (10 \times \text{Acute 2}) + \text{Acute 3}$ > 25 %	3
<sup>a</sup> For the explanation of factor <i>M</i> see 11.3.4.3.4.	

### 11.3.4.3.3 Classification for chronic toxicity (hazard category 1 to hazard category 4)

**11.3.4.3.3.1** All the components of a mixture classified in hazard category 1 of chronic toxicity should be considered for the classification of the mixture. If the sum of these components is greater than 25 % (see table 59), the mixture is classified in hazard category 1 of chronic toxicity. If the result of the calculation (see 11.3.4.1.2) shows a classification of the mixture as hazard category 1 (chronic), the classification procedure is completed.

**11.3.4.3.3.2** In cases where a mixture is not classified in hazard category 1 of chronic toxicity, classification of the mixture in hazard category 2 of chronic toxicity should be considered. A mixture is classified in hazard category 2 of chronic toxicity if 10 times the sum of all the components classified as hazard category 1 (chronic), plus the sum of all the components classified as hazard category 2 (chronic), is greater than 25 %. If the result of the calculation (see 11.3.4.1.2) shows a classification of the mixture as hazard category 2 (chronic), the classification procedure is completed.

**11.3.4.3.3.3** In cases where a mixture is not classified in either hazard categories 1 or 2 of chronic toxicity, classification of the mixture in hazard category 3 of chronic toxicity should be considered. A mixture is classified as hazard category 3 (chronic) if 100 times the sum of all the components classified as hazard category 1 (chronic), plus 10 times the sum of all the components classified as hazard category 2 (chronic), plus the sum of all the components classified as hazard category 3 (chronic), is greater than 25 %.

**11.3.4.3.3.4** In cases where a mixture is not classified in either hazard category 1, 2 or 3, classification of the mixture in hazard category 4 for chronic toxicity should be considered. A mixture is classified as hazard category 4 (chronic) if the sum of the percentages of the components classified as hazard category 1, 2, 3 and 4 is greater than 25 %.

**11.3.4.3.3.5** The classification of mixtures for chronic hazards to the aquatic environment, based on the summation of classified components, is summarized in table 59.

**Table 59 — Classification of mixtures for chronic hazards to the aquatic environment, based on the summation of classified components**

1	2
Sum of components classified as:	Chronic hazard category of the mixture
Chronic 1 $\times M^a$ > 25 %	1
$(M \times 10 \times \text{Chronic 1}) + \text{Chronic 2}$ > 25 %	2
$(M \times 100 \times \text{Chronic 1}) + (10 \times \text{Chronic 2}) + \text{Chronic 3}$ > 25 %	3
Chronic 1 + Chronic 2 + Chronic 3 + Chronic 4 > 25 %	4

<sup>a</sup> For the explanation of factor *M* see 11.3.4.3.4.

Amdt 1

#### 11.3.4.3.4 Classification of mixtures with highly toxic components

Components of a mixture classified in hazard category 1 of acute toxicity and with toxicities ( $LC_{50}$ ,  $EC_{50}$  and  $ErC_{50}$ ) well below 1 mg/L might influence the toxicity of the mixture and should be given increased weight in applying the summation of classification approach. When a mixture contains components classified in hazard category 1 (acute) or hazard category 1 (chronic), the tiered approach (see 11.3.1.3 and flow chart 4) should be applied using a weighted sum by multiplying the concentrations of hazard category 1 (acute) components by a factor, instead of merely adding up the percentages. This means that the concentration of “acute 1” in column 1 of table 58 and the concentration of “chronic 1” in column 1 of table 59 are to be multiplied by the appropriate multiplication factor (*M*) as given in table 60. Therefore, in order to classify a mixture containing components of hazard category 1 (acute and chronic), the correct value of the factor *M* should be known to the person undertaking the classification in order to apply the summation method (see 11.3.4.2). Alternatively, the additivity formula (see 11.3.4.1.2) may be used when toxicity data are available for all highly toxic components in the mixture and there is convincing evidence that all other components, including those for which specific acute toxicity data are not available, are of low or no toxicity and do not significantly contribute to the aquatic environmental hazard of the mixture.

**Table 60 — Multiplication factors for highly toxic components of mixtures**

1	2
Toxicity $L(E)C_{50}$	Multiplication factor ( <i>M</i> )
$0,1 < L(E)C_{50} \leq 1$	1
$0,01 < L(E)C_{50} \leq 0,1$	10
$0,001 < L(E)C_{50} \leq 0,01$	100
$0,0001 < L(E)C_{50} \leq 0,001$	1000
$0,00001 < L(E)C_{50} \leq 0,0001$	10000
(continue in factor 10 intervals)	

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### 11.3.4.3.5 Classification of mixtures with components without any useable information

When no useable information on the acute or the chronic (or both) aquatic hazard is available for one or more components, the mixture cannot be attributed a definitive hazard category(ies). In such a case classification of the mixture shall be based on the known components only and with the additional statement “x percent of the mixture consists of component(s) of unknown hazards to the aquatic environment”.

## 11.4 Hazard communication

The label elements for substances and mixtures hazardous to the aquatic environment are given in table 61. See also:

- a) clause 6 for general and specific considerations concerning labelling;
- b) annex A, *Allocation of label elements*; and
- c) annex B, *Hazard communication and classification summary tables*.

**Table 61 — Label elements for hazards to the aquatic environment**

1	2	3	4
Hazard category	Symbol	Signal word	Hazard statement
<b>ACUTE</b>			
1	Fish and tree	Warning	Very toxic to aquatic life
2	No symbol	No signal word	Toxic to aquatic life
3	No symbol	No signal word	Harmful to aquatic life
<b>CHRONIC</b>			
1	Fish and tree	Warning	Very toxic to aquatic life with long lasting effects
2	Fish and tree	No signal word	Toxic to aquatic life with long lasting effects
3	No symbol	No signal word	Harmful to aquatic life with long lasting effects
4	No symbol	No signal word	May cause long lasting harmful effects to aquatic life

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ASTM-E 1022-94, *Standard guide for conducting bioconcentration tests with fishes and saltwater bivalve molluscs*.

ASTM E 1279-89 (95), *Standard test method for biodegradation by a shake-flask die-away method*.

ASTM E 1625-94, *Standard test method for determining biodegradability of organic chemicals in semi-continuous activated sludge (SCAS)*.

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# **ANNEX A**

## **ALLOCATION OF LABEL ELEMENTS**

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## **Annex A** (normative)

### **Allocation of label elements**

#### **A.1 General**

For the labelling of substances in accordance with GHS the assigned pictogram, the signal word and the hazard statement shall be given in this order for each hazard category of the hazard class. Where the hazard class and categories (or both) are covered in SANS 10228, the assigned corresponding pictogram is given for each category below the GHS requirements.











#### **A.2 Colours of pictograms**

##### **A.2.1 Transport pictograms (hazard labels)**

The colours of the transport pictograms (hazard labels) shall visually match colour reference numbers Pantone 151 or NCS S 0570-Y50R (orange), Pantone 192 or NCS S 0580-Y90R (red), Pantone 361 or NCS S 1565-G (green), Pantone 300 or NCS S 2065-B (blue) and Pantone 109 or NCS S 0570-G90Y (yellow). In case of a dispute the NCS colours shall take precedence. The symbols are in black if not otherwise indicated.



##### **A.2.2 GHS pictograms**





The frame of the GHS pictogram shall visually match Pantone 192 or NCS S 0580-Y90R (red). In case of a dispute the NCS colour shall take precedence. The symbols are in black.

<b>EXPLOSIVES</b>					
<b>Unstable/ Division 1.1</b>	<b>Division 1.2</b>	<b>Division 1.3</b>	<b>Division 1.4</b>	<b>Division 1.5</b>	<b>Division 1.6</b>
 <b>Danger</b> <b>Explosive; mass explosion hazard</b>	 <b>Danger</b> <b>Explosive; severe projection hazard</b>	 <b>Danger</b> <b>Explosive; fire, blast or projection hazard</b>	 <b>Warning</b> <b>Fire or projection hazard</b>	<b>1.5</b> <b>Danger</b> <b>May mass explode in fire</b>	<b>1.6</b>
 (See NOTES 1 and 2)	 (See NOTES 1 and 2)	 (See NOTES 1 and 2)	 (See NOTE 2)	 (See NOTE 2)	 (See NOTE 2)
NOTE 1 Insert the division for explosives (see 9.1.2) in the space marked **. To be left blank if explosive is the subsidiary risk.					
NOTE 2 Insert the compatibility group (See SANS 10228), in the space marked *, denoted by a letter A to N (excluding I and M) as S as indicated in SANS 10228). To be left blank if explosive is the subsidiary risk.					

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FLAMMABLE GASES				
Hazard category 1	Hazard category 2	—	—	Note
 <p><b>Danger</b> Extremely flammable gas</p>	<p>No symbol</p> <p>Warning</p> <p>Flammable gas</p>			<p>In accordance with SANS 10229-1, the symbol, number and borderline may be shown in black instead of white. The background colour stays red in both cases. See also A.2.1</p>
	<p>Not required under SANS 10228</p>			

FLAMMABLE AEROSOLS				
Hazard category 1	Hazard category 2	—	—	Note
 <p><b>Danger</b> Extremely flammable aerosol</p>	 <p><b>Warning</b> Flammable aerosol</p>			<p>In accordance with SANS 10229-1, the symbol, number and the borderline may be shown in black instead of white. The background colour stays red in both cases. See also A.2.1.</p>
				

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OXIDIZING GASES				
Category 1	—	—	—	Note
 <p><b>Danger</b></p> <p>May cause or intensify fire; oxidizer</p>				
				In accordance with SANS 10229-1, the symbol and number are in black and the background is in yellow. See also A.2.1.

GASES UNDER PRESSURE				
Compressed gas	Liquefied gas	Refrigerated liquefied gas	Dissolved gas	Notes
 <p><b>Warning</b></p> <p>Contains gas under pressure; may explode if heated</p>	 <p><b>Warning</b></p> <p>Contains gas under pressure; may explode if heated</p>	 <p><b>Warning</b></p> <p>Contains refrigerated gas; may cause cryogenic burns or injury</p>	 <p><b>Warning</b></p> <p>Contains gas under pressure; may explode if heated</p>	<p>a) Transport pictograms are not required for toxic or flammable gases.</p> <p>b) In accordance with SANS 10229-1, the symbol, number and border line of the transport pictogram may be shown in white instead of black. The background stays green in both cases. See also A.2.1.</p>
				










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FLAMMABLE LIQUIDS				
Hazard category 1	Hazard category 2	Hazard category 3	Hazard category 4	Note
 <p><b>Danger</b> Extremely flammable liquid and vapour</p>	 <p><b>Danger</b> Highly flammable liquid and vapour</p>	 <p><b>Warning</b> Flammable liquid and vapour</p>	<p>No symbol</p> <p><b>Warning</b> Combustible liquid</p>	<p>In accordance with SANS 10229-1, the symbol, number and border line may be shown in black instead of white. The background colour stays red in both cases. See also A.2.1.</p>
			<p>Not required under SANS 10228</p>	



FLAMMABLE SOLIDS				
Category 1	Category 2	—	—	Note
 <p><b>Danger</b> Flammable solid</p>	 <p><b>Warning</b> Flammable solid</p>			<p>In accordance with SANS 10229-1, the symbol and figure are in black and the background is white with seven vertical red stripes See also A.2.1.</p>
				



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<b>SELF-REACTIVE SUBSTANCES</b>				
<b>Type A<sup>a</sup></b>	<b>Type B</b>	<b>Types C and D</b>	<b>Types E and F</b>	<b>Type G</b>
 <p><b>Danger</b> Heating may cause an explosion</p>	  <p><b>Danger</b> Heating may cause a fire or explosion</p>	 <p><b>Danger</b> Heating may cause a fire</p>	 <p><b>Warning</b> Heating may cause a fire</p>	<p>No label elements required</p>
<p>Same as for explosives (follow same symbol selection process)</p>	 			<p>No transport pictogram required under SANS 10229-1</p>
<p><sup>a</sup> Special provision 181, <i>Exemption of explosive label with competent authority approval</i> (see SANS 10228), could apply for a Type B self-reactive substance.</p>				

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PYROPHORIC LIQUIDS				
Hazard category 1	—	—	—	Note
 <p><b>Danger</b></p> <p><b>Catches fire spontaneously if exposed to air</b></p>				<p>In accordance with SANS 10229-1 the colours of the transport pictogram are as follows:</p> <p>a) symbol and figure – black; and</p> <p>b) background – upper half: white lower half: red.</p> <p>See also A.2.1.</p>
				







PYROPHORIC SOLIDS				
Hazard category 1	—	—	—	Note
 <p><b>Danger</b></p> <p><b>Catches fire spontaneously if exposed to air</b></p>				<p>In accordance with SANS 10229-1 the colours of the transport pictogram are as follows:</p> <p>a) symbol and figure – black; and</p> <p>b) background – upper half: white; lower half: red.</p> <p>See also A.2.1.</p>
				



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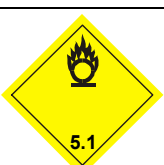
SELF-HEATING SUBSTANCES				
Hazard category 1	Hazard category 2	—	—	Note
 <p><b>Danger</b> Self-heating; may catch fire</p>	 <p><b>Warning</b> Self-heating in large quantities; may catch fire</p>			<p>In accordance with SANS 10229-1, the colours of the transport pictogram are as follows:</p> <p>a) symbol and figure – black; and</p> <p>b) background – upper half: white; lower half: red.</p> <p>See also A.2.1.</p>
				

SUBSTANCES THAT, ON CONTACT WITH WATER, EMIT FLAMMABLE GASES				
Hazard category 1	Hazard category 2	Hazard category 3	—	Note
 <p><b>Danger</b> In contact with water releases flammable gases which may ignite spontaneously</p>	 <p><b>Danger</b> In contact with water releases flammable gases</p>	 <p><b>Warning</b> In contact with water releases flammable gases</p>		<p>In accordance with SANS 10229-1, the symbol, number and border line may be shown in black instead of white. The background stays blue in both cases (see also A.2.1).</p>
				










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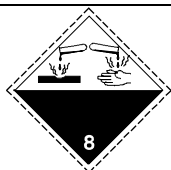
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OXIDIZING LIQUIDS				
Hazard category 1	Hazard category 2	Hazard category 3	—	Note
 <p><b>Danger</b> May cause fire or explosion; strong oxidizer</p>	 <p><b>Danger</b> May intensify fire; oxidizer</p>	 <p><b>Warning</b> May intensify fire; oxidizer</p>		<p>In accordance with SANS 10229-1, the symbol and number are in black and the Background is in yellow . See also A.2.1.</p>
 <p>5.1</p>	 <p>5.1</p>	 <p>5.1</p>		

OXIDIZING SOLIDS				
Category 1	Category 2	Category 3	—	Note
 <p><b>Danger</b> May cause fire or explosion; strong oxidizer</p>	 <p><b>Danger</b> May intensify fire; oxidizer</p>	 <p><b>Warning</b> May intensify fire; oxidizer</p>		<p>In accordance with SANS 10229-1, the symbol and number are in black and the background is in yellow. See also A.2.1.</p>
 <p>5.1</p>	 <p>5.1</p>	 <p>5.1</p>		








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ORGANIC PEROXIDES				
Type A	Type B	Types C and D	Types E and F	Type G
  <b>Danger</b> Heating may cause an explosion	    <b>Danger</b> Heating may cause a fire or explosion	  <b>Danger</b> Heating may cause a fire	  <b>Warning</b> Heating may cause a fire	No label elements allocated to organic peroxides of type G.
Same as for explosives (follow same symbol selection process)	   (See NOTES 1 and 2)	 (See NOTE 2)	 (See NOTE 2)	In accordance with SANS 10228, no transport pictogram is required
NOTE 1 In accordance with Special Provision 181, <i>Exemption of explosive label with competent authority approval</i> (see SANS10228), may apply.  NOTE 2 The transport pictogram conforming to the colour scheme in the tables for oxidizing liquids and oxidizing solids may be used until January 2011 (see also A1.2).				

CORROSIVE TO METALS				
Hazard category 1	—	—	—	Note
  <b>Warning</b> May be corrosive to metals				In accordance with SANS 10229-1:  a) symbol in black and figure “8” in white; and  b) background: upper half in white; lower half in black with white border.
				

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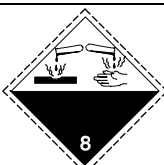
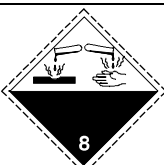
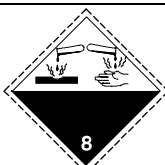
ACUTE TOXICITY: ORAL				
Hazard category 1	Hazard category 2	Hazard category 3	Hazard category 4	Hazard category 5
 <p><b>Danger</b></p> <p>Fatal if swallowed</p>	 <p><b>Danger</b></p> <p>Fatal if swallowed</p>	 <p><b>Danger</b></p> <p>Toxic if swallowed</p>	 <p><b>Warning</b></p> <p>Harmful if swallowed</p>	<p>No symbol</p> <p><b>Warning</b></p> <p>May be harmful if swallowed</p>
			<p>Not required under SANS 10228.</p> <p><b>NOTE:</b> For gases under SANS 10228, replace the number “6” in the bottom corner of the pictogram by “2”.</p>	

ACUTE TOXICITY: SKIN				
Hazard category 1	Hazard category 2	Hazard category 3	Hazard category 4	Hazard category 5
 <p><b>Danger</b></p> <p>Fatal in contact with skin</p>	 <p><b>Danger</b></p> <p>Fatal in contact with skin</p>	 <p><b>Danger</b></p> <p>Toxic in contact with skin</p>	 <p><b>Warning</b></p> <p>Harmful in contact with skin</p>	<p>No symbol</p> <p><b>Warning</b></p> <p>May be harmful in contact with skin</p>
			<p>Not required under SANS 10228.</p> <p><b>NOTE:</b> For gases under SANS 10228, replace the number “6” in the bottom corner of the pictogram by “2”.</p>	

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<b>ACUTE TOXICITY: INHALATION</b>				
Hazard category 1	Hazard category 2	Hazard category 3	Hazard category 4	Hazard category 5
 <p><b>Danger</b> Fatal if inhaled</p>	 <p><b>Danger</b> Fatal if inhaled</p>	 <p><b>Danger</b> Toxic if inhaled</p>	 <p><b>Warning</b> Harmful if inhaled</p>	<p>No symbol</p> <p><b>Warning</b> May be harmful if inhaled</p>
			<p>Not required under SANS 10228. <b>NOTE:</b> For gases under SANS 10228, replace the number “6” in the bottom corner of the pictogram by “2”.</p>	

<b>SKIN CORROSION/IRRITATION</b>				
Hazard category 1A	Hazard category 1B	Hazard category 1C	Hazard category 2	Hazard category 3
 <p><b>Danger</b> Causes severe skin burns and eye damage</p>	 <p><b>Danger</b> Causes severe skin burns and eye damage</p>	 <p><b>Danger</b> Causes severe skin burns and eye damage</p>	 <p><b>Warning</b> Causes skin irritation</p>	<p>No symbol</p> <p><b>Warning</b> Causes mild skin irritation</p>
			<p>Not required under SANS 10228. <b>NOTE:</b> In accordance with SANS 10229-1: a) symbol in black and the figure “8” in white; and b) background: upper half in white; lower half in black with white border.</p>	


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SERIOUS EYE DAMAGE/EYE IRRITATION				
Hazard category 1	Hazard category 2A	Hazard category 2B	—	—
 <p><b>Danger</b> Causes serious eye damage</p>	 <p><b>Warning</b> Causes serious eye irritation</p>	<p>No symbol</p> <p><b>Warning</b> Causes eye irritation</p>		
Transport pictogram not required under SANS 10228.				

RESPIRATORY SENSITIZATION				
Hazard category 1	—	—	—	—
<div></div> <div><p><b>Danger</b></p><p><b>May cause allergy or asthma symptoms or breathing difficulties if inhaled</b></p></div>				
Transport pictogram not required under SANS 10228.				




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SKIN SENSITIZATION				
Hazard category 1	—	—	—	—
<div></div> <div><p>Warning</p><p>May cause an allergic skin reaction</p></div>				
Transport pictogram not required under SANS 10228.				

GERM CELL MUTAGENICITY				
Hazard category 1A	Hazard category 1B	Hazard category 2	—	—
 <p><b>Danger</b></p> <p><b>May cause genetic defects</b> <i>(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard )</i></p>	 <p><b>Danger</b></p> <p><b>May cause genetic defects</b> <i>(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</i></p>	 <p><b>Warning</b></p> <p><b>Suspected of causing genetic defects</b> <i>(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</i></p>		
Transport pictograms not required under SANS 10228.				




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CARCINOGENICITY				
Hazard category 1A	Hazard category 1B	Hazard category 2	—	—
 <p><b>Danger</b></p> <p>May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	 <p><b>Danger</b></p> <p>May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	 <p><b>Warning</b></p> <p>Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>		
Transport pictograms not required under SANS 10228.				



TOXIC TO REPRODUCTION				
Hazard category 1A	Hazard category 1B	Hazard category 2	Additional hazard category	—
 <p><b>Danger</b></p> <p>May damage fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	 <p><b>Danger</b></p> <p>May damage fertility or the unborn child (state specific effect if known)(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	 <p><b>Warning</b></p> <p>Suspected of damaging fertility or the unborn child (state specific effect if known)(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	<p>Effects on or via lactation</p> <p>May cause harm to breast-fed children</p>	
Transport pictograms not required under SANS 10228.				



SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE				
Hazard category 1	Hazard category 2	Hazard category 3	—	—
 <p><b>Danger</b></p> <p>Causes damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	 <p><b>Warning</b></p> <p>May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	 <p><b>Warning</b> (respiratory tract irritation) <b>May cause respiratory irritation</b></p> <p>or</p> <p>(narcotic effects) <b>May cause drowsiness and dizziness</b></p>		
Transport pictograms not required under SANS 10228.				



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SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE				
Hazard category 1	Hazard category 2	—	—	—
 <p><b>Danger</b></p> <p><b>Causes damage to organs (or state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</b></p>	 <p><b>Warning</b></p> <p><b>May cause damage to organs (or state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</b></p>			
Transport pictograms not required under SANS 10228.				

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ASPIRATION HAZARD				
Hazard category 1	Hazard category 2	—	—	—
 <p><b>Danger</b></p> <p>May be fatal if swallowed and enters airways</p>	 <p><b>Warning</b></p> <p>May be harmful if swallowed and enters airways</p>			
Transport pictograms not required under SANS 10228.				

AQUATIC TOXICITY (ACUTE)				
Hazard category 1	Hazard category 2	Hazard category 3	—	Note
 <p><b>Warning</b></p> <p>Very toxic to aquatic life</p>	<p>No symbol</p> <p>No signal word</p> <p>Toxic to aquatic life</p>	<p>No symbol</p> <p>No signal word</p> <p>Harmful to aquatic life</p>		Not covered under SANS 10228 if the substance presents any other hazards covered by SANS 10228. If no other hazard is presented, the class 9 label is applicable (see SANS 10229-1).

AQUATIC TOXICITY (CHRONIC)				
Hazard category 1	Hazard category 2	Hazard category 3	Hazard category 4	Note
 <p><b>Warning</b></p> <p>Very toxic to aquatic life with long lasting effects</p>	 <p>No signal word</p> <p>Toxic to aquatic life with long lasting effects</p>	<p>No symbol</p> <p>No signal word</p> <p>Harmful to aquatic life with long lasting effects</p>	<p>No symbol</p> <p>No signal word</p> <p>May cause long lasting harmful effects to aquatic life</p>	Not covered under SANS 10228 if the substance presents any other hazards covered by SANS 10228. If no other hazard is presented, the class 9 label is applicable (see SANS 10229-1).

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# **ANNEX B**

## **HAZARD COMMUNICATION AND CLASSIFICATION**

### **SUMMARY TABLES**

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## **Annex B**

(normative)

### **Hazard communication and classification summary tables**

#### **B.1 Hazard statements**

##### **B.1.1 General**

**B.1.1.1** For the purposes of this standard, a code is assigned to each of the hazard statements (see 3.1.45) applicable to the hazard categories defined under the GHS.

**B.1.1.2** The hazard statement codes shall only be used for reference purposes and shall neither form part of the hazard statement text that appears on a GHS label, nor replace it.

##### **B.1.2 Codification of hazard statements**

**B.1.2.1** Hazard statements are assigned a unique alphanumeric code that consists of one letter and three numbers as follows:

- a) the letter "H" for "hazard statement";
- b) a number designating the type of hazard to which the hazard statement is assigned:
  - 1) "2" for physical hazards
  - 2) "3" for health hazards
  - 3) "4" for environmental hazards; and
- c) two numbers corresponding to the sequential numbering hazards arising from the intrinsic properties of the substance or mixture, for example code numbers 200 to 210 for explosivity and code numbers 220 to 230 for flammability.

**B.1.2.2** The codes are listed, in numerical order, in B.1.3. The text in regular font is the text that shall appear on the label. The text in italics and enclosed within brackets provides extra information that could be specified. In such cases, the manufacturer or supplier can choose, or the competent authority can prescribe, the information.

##### **B.1.3 Hazard statement codes**

###### **B.1.3.1 Physical hazard statements**

<b>H200</b>	Unstable explosive
<b>H201</b>	Explosive; mass explosion hazard
<b>H202</b>	Explosive; severe projection hazard
<b>H203</b>	Explosive; fire blast or projection hazard
<b>H204</b>	Fire or projection hazard
<b>H205</b>	May explode in fire
<b>H220</b>	Extremely flammable gas
<b>H221</b>	Flammable gas

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- H222** Extremely flammable aerosol
- H223** Flammable aerosol
- H224** Extremely flammable liquid and vapour
- H225** Highly flammable liquid and vapour
- H226** Flammable liquid and vapour
- H227** Combustible liquid
- H228** Flammable solid
  
- H240** Heating may cause an explosion
- H241** Heating may cause a fire or explosion
- H242** Heating may cause a fire
  
- H250** Catches fire spontaneously if exposed to air
- H251** Self-heating; may catch fire
- H252** Self-heating in large quantities; may catch fire
  
- H260** In contact with water releases flammable gases that may ignite spontaneously
- H261** In contact with water releases flammable gas
  
- H270** May cause or intensify fire; oxidizer
- H271** May cause fire or explosion; strong oxidizer
- H272** May intensify fire; oxidizer
  
- H280** Contains gas under pressure; may explode if heated
- H281** Contains refrigerated gas; may cause cryogenic burns or injury
  
- H290** May be corrosive to metals

### **B.1.3.2 Health hazard statements**

- H300** Fatal if swallowed
- H301** Toxic if swallowed
- H302** Harmful if swallowed
- H303** May be harmful if swallowed
- H304** May be fatal if swallowed and enters airways
- H305** May be harmful if swallowed and enters airways
  
- H310** Fatal in contact with skin
- H311** Toxic in contact with skin
- H312** Harmful in contact with skin
- H313** May be harmful in contact with skin
- H314** Causes severe skin burns and eye damage
- H315** Causes skin irritation
- H316** Causes mild skin irritation
- H317** May cause an allergic skin reaction
- H318** Causes severe eye damage
- H319** Causes severe eye irritation
- H320** Causes eye irritation
  
- H330** Fatal if inhaled
- H331** Toxic if inhaled
- H332** Harmful if inhaled
- H333** May be harmful if inhaled
- H334** May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H335** May cause respiratory irritation

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- H336** May cause drowsiness or dizziness
- H340** May cause genetic defects (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*)
- H341** Suspected of causing genetic defects (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*)
- H350** May cause cancer (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*)
- H351** Suspected of causing cancer (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*)
- H360** May damage fertility or the unborn child (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*)
- H361** Suspected of damaging fertility or the unborn child (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*)
- H362** May cause harm to breast-fed children
- H370** Causes damage to organs (*or state all organs affected, if known*) (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*)
- H371** May cause damage to organs (*or state all organs affected, if known*) (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*)
- H372** Causes damage to organs (*state all organs affected, if known*) through prolonged or repeated exposure (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*) **Amdt 1**
- H373** May cause damage to organs (*state all organs affected, if known*) through prolonged or repeated exposure (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*) **Amdt 1**

### B.1.3.3 Environmental hazard statements

- H400** Very toxic to aquatic life
- H401** Toxic to aquatic life
- H402** Harmful to aquatic life **Amdt 1**
- H410** Very toxic to aquatic life with long lasting effects
- H411** Toxic to aquatic life with long lasting effects
- H412** Harmful to aquatic life with long lasting effects
- H413** May cause long lasting harmful effects to aquatic life

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### **B.2 Precautionary statements**

#### **B.2.1 General**

**B.2.1.1** For the purposes of this standard, a code is assigned to each of the precautionary statements (see 3.1.63) applicable to the hazard categories defined in the GHS. The precautions are divided into five types (see B.2.2.1).

**B.2.1.2** The precautionary statements shall only be used for reference purposes and shall neither form part of the precautionary statement text that appears on the GHS label, or replace it.

#### **B.2.2 Codification of precautionary statements**

**B.2.2.1** Precautionary statements are assigned a unique alphanumerical code that consists of one letter and three numbers as follows:

- a) the letter "P" for "precautionary statement";
- b) a number designating the type of precaution to be taken:
  - 1) "1" for general precautions
  - 2) "2" for the prevention of a hazardous situations
  - 3) "3" for the response in case of accidental spillage or exposure, emergency response and first aid
  - 4) "4" for storage
  - 5) "5" for disposal; and
- c) two numbers corresponding to the sequential numbering of the precautionary statements.

**B.2.2.2** The codes are listed, in numerical order, in B.2.5. The text in regular font is the text that shall appear on the label. The text in italics indicates specific conditions that apply to the use or allocation of the precautionary statement, for example "Use explosion-proof electrical equipment *if dust clouds can occur*" is only applicable to flammable solids. Text in regular font and enclosed in brackets indicates additional information that is required or needs to be specified.

**B.2.2.3** A backslash (/) in the text of a precautionary statement indicates that a choice has to be made between the phrases it separates, for example "Wear protective gloves/protective clothing/eye protection/face shield". In such a case, the manufacturer or supplier should choose the most appropriate phrase(s).

**B.2.2.4** Three full stops (...) in the text of a precautionary statement indicate that all applicable conditions are not listed, for example "Use explosion-proof electrical/ventilation/lighting/.../equipment" indicates that other equipment might need to be specified. In such a case, the manufacturer or supplier can choose the other conditions to be specified.

**B.2.2.5** A number of different precautionary statements can be combined. This is indicated in B.3 to B.22 by codes joined with a plus sign (+). For example, "P305 + P351 + P338 indicates that the text on the label should read "IF IN THE EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing".

## **B.2.3 Use of precautionary statements**

### **B.2.3.1 General**

**B.2.3.1.1** Classification of a chemical is the starting point for the assignment of precautionary statements. In the majority of cases, the recommended precautionary statements are independent, for example, the statements for explosive hazard do not modify the statements related to health hazards. Therefore, chemicals that are classified for both hazard classes shall bear precautionary statements for both.

**B.2.3.1.2** To protect people with different reading abilities, precautionary pictograms (see B.32) could be depicted on the label in addition to the precautionary statements.

NOTE The pictograms in B.32 do not cover all precautionary aspects to be addressed.

### **B.2.3.2 Allocation of precautionary statements**

**B.2.3.2.1** For the allocation of precautionary statements, all the specific elements relating to the particular hazard classes shall be taken into account.

**B.2.3.2.2** Where a substance or a mixture is classified for a number of health hazards, the most stringent set of precautionary statements shall be selected. This applies mainly for preventative measures where rapid response is crucial. For example, if a substance is classified as carcinogenic and acutely toxic, the first-aid measures for acute toxicity take precedence over those for longer-term effects. In addition, incidental exposure might result in delayed health effects, which might require medical attention.

**B.2.3.2.3** The combination of precautionary statements is encouraged to provide flexibility in the application of precautionary statements, save label space and improve readability. The combination of precautionary statements can also be useful for different types of hazards where the precautionary behaviour is similar, for example, "Keep away from heat, sparks and open flame and store in a well-ventilated place".

**B.2.3.2.4** Precautionary statements shall appear on the GHS labels along with the GHS hazard communication elements (pictograms, signal words and hazard statements). Additional supplemental information such as directions for use might also be provided at the discretion of the manufacturer, or supplier, or the competent authority as applicable. For some chemicals, first aid, treatment measures, specific antidotes and cleansing material could be required. In such cases, the advice of poison centres and medical practitioners should be sought and included on the label.

## **B.2.4 General precautionary measures**

**B.2.4.1** General precautionary measures shall be adopted for all substances and mixtures that are classified as hazardous to human health or the environment. To this end, the needs of, and the information sources available to the general public, the commercial user and the industrial worker shall be taken into account.

**B.2.4.2** The precautionary label information, specific safety guidelines and the information in a safety data sheet, all form part of the labelling requirements and occupational health and safety procedures that need to be taken into account before a substance is used.

**B.2.4.3** In order to correctly implement precautionary measures concerning prevention, response, storage and disposal, it is necessary to have information on the composition of the products at hand available, so that the information shown on the container, label and safety data sheet be taken into account when asking for further specialist advice.

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### **B.2.5 Precautionary statement codes**

#### **B.2.5.1 General**

- P101** If medical advice is needed, have product container or label at hand
- P102** Keep out of reach of children
- P103** Read label before use

#### **B.2.5.2 Prevention precautionary statements**

- P201** Obtain special instructions before use
- P202** Do not handle until all safety precautions have been read and understood
- P210** Keep away from heat/sparks/open flames/hot surfaces – No smoking  
(manufacturer/supplier or the competent authority to specify applicable ignition sources)
- P211** Do not spray on an open flame or other ignition source
- P220** Keep/Store away from clothing/.../combustible materials (manufacturer/supplier or the competent authority to specify other incompatible materials)
- P221** Take any precaution to avoid mixing with combustibles/... (manufacturer/supplier or the competent authority to specify incompatible materials)
- P222** Do not allow contact with air
- P223** Keep away from any possible contact with water, because of violent reaction and possible flash fire
- P230** Keep wetted with ... (manufacturer/supplier or the competent authority to specify appropriate material)
  - *if drying out increases explosion hazard, except as needed for manufacturing or operating processes (for example nitrocellulose)*
- P231** Handle under inert gas
- P232** Protect from moisture
- P233** Keep container tightly closed
  - *if product is volatile so as to generate hazardous atmosphere*
- P234** Keep only in original container
- P235** Keep cool
- P240** Ground/bond container and receiving equipment
  - *if the explosive is electrostatically sensitive*
  - *if electrostatically sensitive material if for reloading*
  - *if product is volatile so as to generate hazardous atmosphere*
- P241** Use explosion-proof electrical/ventilation/.../equipment (manufacturer/supplier or the competent authority to specify other equipment)
  - *if dust clouds can occur (only applicable to flammable solids)*
- P242** Use only non-sparking tools
- P243** Take precautionary measures against static discharge

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- P244** Keep reduction valves free from grease and oil
- P250** Do not subject to grinding/shock/.../friction (manufacturer/supplier or the competent authority to specify applicable rough handling)
- P251** Pressurized container: Do not pierce or burn, even after use
- P260** Do not breathe dust/fume/gas/mist/vapours/spray (manufacturer/supplier or the competent authority to specify applicable conditions)
- P261** Avoid breathing dust/fume/gas/mist/vapours/spray (manufacturer/supplier or the competent authority to specify applicable conditions)
- P262** Do not get in eyes, on skin, or on clothing
- P263** Avoid contact during pregnancy/while nursing
- P264** Wash ...thoroughly after handling (manufacturer/supplier or the competent authority to specify parts of the body to be washed after handling)
- P270** Do not eat, drink or smoke when using this product
- P271** Use only outdoors or in well ventilated area
- P272** Contaminated work clothing should not be allowed out of the workplace
- P273** Avoid release to the environment  
– *if this is not the intended use*
- P280** Wear protective gloves/protective clothing/eye protection/face protection  
(manufacturer/supplier or the competent authority to specify the type of equipment)
- P281** Use personal protective equipment as required
- P282** Wear cold insulating gloves/face shield/eye protection
- P283** Wear fire/flame-resistant/retardant clothing
- P284** Wear respiratory protection (manufacturer/supplier or the competent authority to specify equipment)
- P285** In case of inadequate ventilation wear respiratory protection (manufacturer/supplier or the competent authority to specify equipment)
- P231+P232** Handle under inert gas and protect from moisture
- P235+P410** Keep cool and protect from sunlight

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### **B.2.5.3 Response precautionary statements**

#### **B.2.5.3.1 Single response precautionary statements**

**P301** IF SWALLOWED:

**P302** IF ON SKIN:

**P303** IF ON SKIN (or hair):

**P304** IF INHALED:

**P305** IF IN EYES:

**P306** IF ON CLOTHING:

**P307** IF EXPOSED:

**P308** IF EXPOSED OR CONCERNED:

**P309** IF EXPOSED OR IF YOU FEEL UNWELL:

**P310** Immediately call a POISON CENTRE or doctor/physician

**P311** Call a POISON CENTRE or doctor/physician

**P312** Call a POISON CENTRE or doctor/physician if you feel unwell

**P313** Get medical advice/attention

**P314** Get medical advice/attention if you feel unwell

**P315** Immediately get medical advice/attention

**P320** Specific treatment is urgent (see...on this label) (reference to supplemental first-aid instruction)

– *if immediate administration of antidote is required*

**P321** Specific treatment (see...on this label) (reference to supplemental first-aid instruction)

**P322** Specific measures (see...on this label) (...Reference to supplemental first aid instruction)

**P330** Rinse mouth

**P331** Do NOT induce vomiting

**P332** If skin irritation occurs:

**P333** If skin irritation or rash occurs:

**P334** Immerse in cool water/wrap in wet bandages

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**P335** Brush off loose particles from skin

**P336** Thaw frosted parts with lukewarm water. Do not rub affected area

**P337** If eye irritation persists:

**P338** Remove contact lenses, if present and easy to do. Continue rinsing

**P340** Remove to fresh air and keep at rest in a position comfortable for breathing

**P341** If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing

**P342** If experiencing respiratory symptoms:

**P350** Gently wash with plenty of soap and water

**P351** Rinse cautiously with water for several minutes

**P352** Wash with plenty of water

**P353** Rinse skin with water/shower

**P360** Rinse immediately contaminated clothing and skin with plenty of water before removing clothes

**P361** Immediately remove/take off all contaminated clothing

- P362** Take off contaminated clothing and wash before re-use  
**P363** Wash contaminated clothing before re-use
- P370** In case of fire:
- P371** In case of major fire and large quantities:  
**P372** Explosion risk in case of fire  
**P373** DO NOT fight fire when fire reaches explosives  
**P374** Fight fire with normal precautions from a reasonable distance  
**P375** Fight fire at a distance owing to the risk of explosion
- P376** Stop leak if safe to do so  
**P377** Leaking gas fire: Do not extinguish, unless leak can be stopped safely
- P378** Use...for extinction (manufacturer/supplier or the competent authority to specify appropriate media)  
 – *if water increases risk*
- P380** Evacuate area  
**P381** Eliminate all ignition sources if safe to do so
- P390** Absorb spillage to prevent material damage  
**P391** Collect spillage

#### **B.2.5.3.2 Combined response precautionary statements**

- P301+P310** IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
- P301+P312** IF SWALLOWED: Call a POISON CENTRE or doctor /physician if you feel unwell
- P301+P330+P331** IF SWALLOWED: Rinse mouth. Do not induce vomiting
- P302+P334** IF ON SKIN: Immerse in cool water/wrap in wet bandages
- P302+P350** IF ON SKIN: Gently wash with plenty of soap and water
- P302+P352** IF ON SKIN: Wash with plenty of soap and water
- P303+P361+P353** IF ON SKIN (or hair): Immediately remove/take off all contaminated clothing. Immediately rinse skin with water/shower
- P304+P312** IF INHALED: Call a POISON CENTRE or doctor/physician if you feel unwell
- P304+P340** IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
- P304+P341** IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
- P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

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**P306+P360** IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes

**P307+P311** IF EXPOSED: Call a POISON CENTRE or doctor/physician

**P308+P313** If exposed or concerned: Call a POISON CENTRE or doctor/physician

**P309+P311** If exposed or if you feel unwell: Call a POISON CENTRE or doctor/physician

**P332+P313** If skin irritation occurs: Get medical advice/attention

**P333+P313** If skin irritation or rash occurs: Get medical advice/attention

**P335+P334** Brush off loose particles from skin. Immerse in cool water/wrap in wet bandages

**P337+P313** If eye irritation persists: Get medical advice/attention

**P342+P311** If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician

**P370+P376** In case of fire: Stop leak if safe to do so

**P370+P378** In case of fire: use ... for extinction – *if water increases risk*

**P370+P380** In case of fire: Evacuate area

**P370+P380+P375** In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion

**P371+P380+P375** In case of major fire or large quantities: Evacuate area. Fight fire at a distance owing to the risk of explosion

### B.2.5.4 Storage precautionary statements

#### B.2.5.4.1 Single precautionary statements

**P401** Store in accordance with national regulations (*to be specified*) **Amdt 1**

**P402** Store in a dry place

**P403** Store in a well ventilated place - *if product is volatile so as to generate a hazardous atmosphere* **Amdt 1**

**P404** Store in a closed container

**P405** Store locked up

**P406** Store in corrosive resistant/...container with a resistant inner liner

**P407** Maintain air gap between stacks/pallets

**P410** Protect from sunlight

**P411** Store at temperatures not exceeding ...°C

**P412** Do not expose to temperatures exceeding 50 °C

**P413** Store bulk masses greater than...kg at temperatures not exceeding ...°C

**P420** Store away from other materials

**P422** Store contents under ...

#### B.2.5.4.2 Combined storage precautionary statements

**P402+P404** Store in a dry place in a closed container

**P403+P233** Store in a well-ventilated place and keep the container tightly closed

**P403+P235** Store in a well-ventilated place and keep cool

**P410+P403** Protect from sunlight and store in a well-ventilated place

**P410+P412** Protect from sunlight and do not expose to temperatures exceeding 50 °C

**P411+P235** Store at temperatures not exceeding ...°C. Keep cool





### B.2.5.5 Disposal precautionary statements

**P501** Dispose of contents/container to ...

**B10**



### B.3 Explosives (see 9.1 for details)


Hazard category	Criteria	Hazard communication elements	
<b>Unstable explosives</b>	According to the results of the test in Part I of the <i>UN Manual of tests and criteria</i> .	Symbol	
		Signal word	Danger
		Hazard statement	H200
		Precautionary statements	P201; P202; P281, P372; P373; P380; P401; P501
<b>Division 1.1</b>	According to the results of the test in Part I of the <i>UN Manual of tests and criteria</i> .	Symbol	
		Signal word	Danger
		Hazard statement	H201
		Precautionary statements	P201; P230; P240; P250; P280; P370+P380; P372; P373; P401; P501
<b>Division 1.2</b>	According to the results of the test in Part I of the <i>UN Manual of tests and criteria</i> .	Symbol	
		Signal word	Danger
		Hazard statement	H202
		Precautionary statements	P201; P230; P240; P250; P280; P370+P380; P372; P373; P401; P501
<b>Division 1.3</b>	According to the results of the test in Part I of the <i>UN Manual of tests and criteria</i> .	Symbol	
		Signal word	Danger
		Hazard statement	H203
		Precautionary statements	P201; P230; P240; P250; P280; P370+P380; P372; P373; P401; P501

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### B.3 Explosives *(concluded)*



Hazard category	Criteria	Hazard communication elements	
<b>Division 1.4</b>	According to the results of the tests in Part I of the UN <i>Manual of tests and criteria</i>	Symbol	
		Signal word	Warning
		Hazard statement	H204
		Precautionary statements	P210; P240; P250; P280; P370+P380; P372; P373; P374; P401; P501
<b>Division 1.5</b>	According to the results of the test in Part I of the UN <i>Manual of tests and criteria</i> .	Symbol	<b>1.5</b>
		Signal word	Danger
		Hazard statement	H205
		Precautionary statements	P210; P230; P240; P250; P280; P370+P380; P372; P373; P401; P501
<b>Division 1.6</b>	According to the results of the test in Part I of the UN <i>Manual of tests and criteria</i> .	Symbol	<b>1.6</b>
		Signal word	None
		Hazard statement	None
		Precautionary statements	P210; P240; P373; P401; P501

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**B.4 Flammable gases** (see 9.2 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b>	Gases and gas mixtures that, at 20 °C and a standard pressure of 101,3 kPa:  a) are ignitable when in a mixture of 13 % or less by volume in air; or  b) have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit.	Symbol	
		Signal word	Danger
		Hazard statement	H220
		Precautionary statements	P210; P377; P381; P403
<b>2</b>	Gases or gas mixtures, other than those of category 1, which, at 20 °C and a standard pressure of 101,3 kPa, have a flammable range while mixed in air.	Symbol	None
		Signal word	Warning
		Hazard statement	H221
		Precautionary statements	P310; P377; P401

**B.5 Flammable aerosols** (see 9.3 for details)


Hazard category	Criteria	Hazard communication elements	
<b>1</b>	On the basis of its components, of its chemical heat of combustion and, if applicable, of the results of the foam test, for foam aerosols, and of the ignition distance test and enclosed space test, for spray aerosols (see Part III, section 31 of the UN <i>Manual of tests and criteria</i> ).	Symbol	
		Signal word	Danger
		Hazard statement	H222
		Precautionary statements	P210; P211; P251; P410+P412
<b>2</b>	On the basis of its components, of its chemical heat of combustion and, if applicable, of the results of the foam test, for foam aerosols, and of the ignition distance test and enclosed space test, for spray aerosols (see Part III, section 31 of the UN <i>Manual of tests and criteria</i> ).	Symbol	
		Signal word	Warning
		Hazard statement	H223
		Precautionary statements	P210; P211; P251; P410+P412

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### B.6 Oxidizing gases (see 9.4 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b>	Any gas that may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.	Symbol	
		Signal word	Danger
		Hazard statement	H270
		Precautionary statements	P220; P244; P370+P376; P403




## B.7 Gases under pressure (see 9.5 for details)

Hazard category	Criteria	Hazard communication elements	
<b>Compressed gas</b>	A gas that, when packaged under pressure, is entirely gaseous at $-50\text{ }^{\circ}\text{C}$ ; including all gases with a critical temperature $\leq -50\text{ }^{\circ}\text{C}$ .	Symbol	
		Signal word	Warning
		Hazard statement	H280
		Precautionary statements	P410+P403
<b>Liquefied gas</b>	A gas that, when packaged under pressure, is partially liquid at temperatures above $-50\text{ }^{\circ}\text{C}$ .  A distinction is made between:  a) <i>High pressure liquefied gas</i> : a gas with a critical temperature between $-50\text{ }^{\circ}\text{C}$ and $+65\text{ }^{\circ}\text{C}$ ; and  b) <i>Low pressure liquefied gas</i> : a gas with a critical temperature above $+65\text{ }^{\circ}\text{C}$	Symbol	
		Signal word	Warning
		Hazard statement	H280
		Precautionary statements	P410+P403
<b>Refrigerated liquefied gas</b>	A gas that, when packaged, is made partially liquid because of its low temperature.	Symbol	
		Signal word	Warning
		Hazard statement	H281
		Precautionary statements	P282; P336; P403
<b>Dissolved gas</b>	A gas that, when packaged under pressure, is dissolved in a liquid phase solvent.	Symbol	
		Signal word	Warning
		Hazard statement	H280
		Precautionary statements	P410+P403

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### B.8 Flammable liquids (see 9.6 for details)

Hazard category	Criteria <sup>a</sup>	Hazard communication elements	
1	Flash point < 23 °C and initial boiling point ≤ 35 °C.	Symbol	
		Signal word	Danger
		Hazard statement	H224
		Precautionary statements	P210; P233; P240; P241; P242; P243; P280; P303+P361+P353; P370+P378; P403+P235; P501
2	Flash point < 23 °C and initial boiling point >35 °C.	Symbol	
		Signal word	Danger
		Hazard statement	H225
		Precautionary statements	P210; P233; P240; P241; P242; P243; P280; P303+P361+P353; P370+P378; P403+P235; P501
3	Flash point ≥ 23 °C and ≤ 60 °C	Symbol	
		Signal word	Warning
		Hazard statement	H226
		Precautionary statements	P210; P233; P240; P241; P242; P243; P280; P303+P361+P353; P370+P378; P403+P235; P501

<sup>a</sup> See annex A of SANS 10228 for the test methods.



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### B.8 Flammable liquids (*concluded*)

Hazard category	Criteria <sup>a</sup>	Hazard communication elements	
4	Flash point > 60 °C and ≤ 93 °C	Symbol	None
		Signal word	Warning
		Hazard statement	H227
		Precautionary statements	P210; P280; P370+P378; P403+-235; P501
<sup>a</sup> See annex A of SANS 10228 for the test methods.			

### B.9 Flammable solids (see 9.7 for details)




Hazard category	Criteria <sup>a</sup>	Hazard communication elements	
1	<b>Burning rate test</b>  <i>a Substances and mixtures other than metal powders</i>  The wetted zone does not stop the fire and the burning time is < 45 s, or the burning rate is > 2,2 mm/s  <i>b) Metal powders</i>  The burning time is ≤ 5 min.	Symbol	
		Signal word	Danger
		Hazard statement	H228
		Precautionary statements	P210; P240; P241; P280; P370+P378
2	<b>Burning rate test</b>  <i>a) Substances and mixtures other than metal powders</i>  The wetted zone stops the fire for at least 4 minutes and the burning time is < 45 s, or the burning rate is >2,2 mm/s  <i>b) Metal powders</i>  The burning time is > 5 min and ≤ 10 min	Symbol	
		Signal word	Warning
		Hazard statement	H228
		Precautionary statements	P210; P240; P241; P280; P370+P378

<sup>a</sup> See annex A of SANS 10228 for the test methods.

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### B.10 Self-reactive substances (see 9.8 for details)


Hazard category	Criteria	Hazard communication elements	
<b>Type A</b>	According to the results of the tests in Part II, Section 20.4.2 of the UN <i>Manual of tests and criteria</i> .	Symbol	
		Signal word	Danger
		Hazard statement	H240
		Precautionary statements	P210; P220; P234; P280; P370+P378; P370+P380+P375; P403+P235; P411; P420; P501
<b>Type B</b>	According to the results of the tests in Part II, Section 20.4.2 of the UN <i>Manual of tests and criteria</i> .	Symbol	
		Signal word	Danger
		Hazard statement	H241
		Precautionary statements	P210; P220; P234; P280; P370+P378; P370+P380+P375; P403+P235; P411; P420; P501
<b>Types C and D</b>	According to the results of the tests in Part II, Section 20.4.2 of the UN <i>Manual of tests and criteria</i> .	Symbol	
		Signal word	Danger
		Hazard statement	H242
		Precautionary statements	P210; P220; P234; P280; P370+P378; P403+P235; P411; P420; P501

<sup>a</sup> See annex A of SANS 10228 for the test methods.


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## B.10 Self-reactive substances *(concluded)*

Hazard category	Criteria	Hazard communication elements	
<b>Types E and F</b>	According to the results of the tests in Part II, Section 20.4.2 of the UN <i>Manual of tests and criteria</i> .	Symbol	
		Signal word	Warning
		Hazard statement	H242
		Precautionary statements	P210; P220; P234; P280; P370+P378; P403+P235; P411; P420; P501
<b>Type G</b>	According to the results of the tests in Part II, Section 20.4.2 of the UN <i>Manual of tests and criteria</i> .	Symbol	No label elements are allocated to this hazard category
		Signal word	
		Hazard and precautionary statements	

## B.11 Pyrophoric liquids (see 9.9.1.1 for details)


Hazard category	Criteria <sup>a</sup>	Hazard communication elements	
1	The liquid ignites within 5 min when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min.	Symbol	
		Signal word	Danger
		Hazard statement	H250
		Precautionary statements	P210; P222; P280; P302+P334; P370+P378; P422

<sup>a</sup> See annex A of SANS 10228 for the test methods.



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### B.12 Pyrophoric solids (see 9.9.1.2 for details)

Hazard category	Criteria <sup>a</sup>	Hazard communication elements	
1	The solid ignites within 5 min of coming into contact with air.	Symbol	
		Signal word	Danger
		Hazard statement	H250
		Precautionary statements	P210; P222; P280; P335+P334; P370+P378; P422
<sup>a</sup> See annex A of SANS 10228 for the test methods.			

### B.13 Self-heating substances (see 9.10 for details)

Hazard category	Criteria	Hazard communication elements	
1	A positive result is obtained in a test using a cubical container of sides 25 mm at 140 °C.	Symbol	
		Signal word	Danger
		Hazard statement	H251
		Precautionary statements	P235+410; P280; P407; P413; P420
2	a) A positive result is obtained in a test using a cubical container of sides 100 mm at 140 °C and a negative result is obtained in a test using a cubical container of sides 25 mm at 140 °C <u>and</u> the substance is to be packed in packages with a volume of more than 3 m <sup>3</sup> ; or  b) a positive result is obtained in a test using a cubical container of sides 100 mm at 140 °C and a negative result is obtained in a test using a 25 mm cube sample at 140 °C, a positive result is obtained in a test using a cubical container of sides 100 mm at 120 °C <u>and</u> the substance is to be packed in packages with a volume of more than 450 litres; or  c) a positive result is obtained in a test using a cubical container of sides 100 mm at 140 °C and a negative result is obtained in a test using a cubical container of sides 25 mm at 140 °C <u>and</u> a positive result is obtained in a test using a cubical container of sides 100 mm at 100 °C.	Symbol	
		Signal word	Warning
		Hazard statement	H252
		Precautionary statements	P235+410; P280; P407; P413; P420




<sup>a</sup> See annex A of SANS 10228 for the test methods

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### B.14 Substances that, on contact with water, emit flammable gases

(see 9.11 for details)




Hazard category	Criteria <sup>a</sup>	Hazard communication elements	
1	Any substance that reacts vigorously with water at ambient temperatures and demonstrates a tendency for the gas produced to ignite spontaneously, or that reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 L/kg of substance over any 1 min.	Symbol	
		Signal word	Danger
		Hazard statement	H260
		Precautionary statements	P223; P231+P232; P280; P335+P334; P370+P378; P402+P404; P501
2	Any substance that reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 L/kg of substance per hour, and that does not meet the criteria for category 1.	Symbol	
		Signal word	Danger
		Hazard statement	H261
		Precautionary statements	P223; P231+P232; P280; P335+P334; P370+P378; P402+P404; P501
3	Any substance that reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 1 L/kg of substance per hour, and that does not meet the criteria for categories 1 and 2.	Symbol	
		Signal word	Warning
		Hazard statement	H261
		Precautionary statements	P231+P232; P280; P370+P378; P402+P404; P501

<sup>a</sup> See annex A of SANS 10228 for the test methods.

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**B.15 Oxidizing liquids** (see 9.12.2.1 for details)




Hazard category	Criteria <sup>a</sup>	Hazard communication elements	
1	Any substance that, in the 1:1 mixture, by mass, of substance and cellulose tested, spontaneously ignites; or the mean pressure rise time of a 1:1 mixture, by mass, of substance and cellulose is less than that of a 1:1 mixture, by mass, of 50 % perchloric acid and cellulose.	Symbol	
		Signal word	Danger
		Hazard statement	H271
		Precautionary statements	P210; P220; P221; P280; P283; P306+P360; P371+P380+P375; P370+P378; P501
2	Any substance that, in the 1:1 mixture, by mass, of substance and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40 % aqueous sodium chlorate solution and cellulose; and the criteria for category 1 are not met.	Symbol	
		Signal word	Danger
		Hazard statement	H272
		Precautionary statements	P210; P220; P221; P280; P370+P378; P501
3	Any substance that, in the 1:1 mixture, by mass, of substance and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65 % aqueous nitric acid and cellulose; and the criteria for categories 1 and 2 are not met.	Symbol	
		Signal word	Warning
		Hazard statement	H272
		Precautionary statements	P210; P220; P221; P280; P370+P378; P501
<sup>a</sup> See annex A of SANS 10228 for the test methods.			

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### B.16 Oxidizing solids (see 9.12.2.2 for details)

Hazard category	Criteria <sup>a</sup>	Hazard communication elements	
1	Any substance that, in the 4:1 or 1:1 sample-to-cellulose ratio, by mass, exhibits a mean burning time less than the mean burning time of a 3:2 mixture, by mass, of potassium bromate and cellulose.	Symbol	
		Signal word	Danger
		Hazard statement	H271
		Precautionary statements	P210; P220; P221; P280; P283; P306+P360; P371+P380+P375; P370+P378; P501
2	Any substance that, in the 4:1 or 1:1 sample-to-cellulose ratio, by mass, exhibits a mean burning time equal to or less than the mean burning time of a 2:3 mixture, by mass, of potassium bromate and cellulose and the criteria for category 1 are not met.	Symbol	
		Signal word	Danger
		Hazard statement	H272
		Precautionary statements	P210; P220; P221; P280; P370+P378; P501
3	Any substance that, in the 4:1 or 1:1 sample-to-cellulose ratio, by mass, exhibits a mean burning time equal to or less than the mean burning time of a 3:7 mixture, by mass, of potassium bromate and cellulose and the criteria for categories 1 and 2 are not met.	Symbol	
		Signal word	Warning
		Hazard statement	H272
		Precautionary statements	P210; P220; P221; P280; P370+P378; P501

<sup>a</sup> See annex A of SANS 10228 for the test methods.


## B.17 Organic peroxides (see 9.13 for details)

Hazard category	Criteria	Hazard communication elements	
<b>Type A</b>	According to the results of test series A to H in the Part II, Section 20.4.3 of the <i>UN Manual of tests and criteria</i> .	Symbol	
		Signal word	Danger
		Hazard statement	H240
		Precautionary statements	P210; P220; P234; P280; P411+P235; P410; P420; P501
<b>Type B</b>	According to the results of test series A to H in the Part II, Section 20.4.3 of the <i>UN Manual of tests and criteria</i>	Symbol	
		Signal word	Danger
		Hazard statement	H241
		Precautionary statements	P210; P220; P234; P280; P411+P235; P410; P420; P501
<b>Type C and D</b>	According to the results of test series A to H in the Part II, Section 20.4.3 of the <i>UN Manual of tests and criteria</i>	Symbol	
		Signal word	Danger
		Hazard statement	H242
		Precautionary statements	P210; P220; P234; P280; P411+P235; P410; P420; P501
<b>Type E and F</b>	According to the results of test series A to H in the Part II, Section 20.4.3 of the <i>UN Manual of tests and criteria</i>	Symbol	
		Signal word	Warning
		Hazard statement	H242
		Precautionary statements	P210; P220; P234; P280; P411+P235; P410; P420; P501
<b>Type G</b>	According to the results of test series A to H in the Part II, Section 20.4.3 of the <i>UN Manual of tests and criteria</i>	Signal word	No label elements allocated to this hazard category
		Symbol	
		Hazard statement	

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### B.18 Corrosive to metals (see 9.14 for details)

Hazard category	Criteria <sup>a</sup>	Hazard communication elements	
1	Corrosion rate on steel or aluminium surfaces exceeding 6,25 mm/year at 55 °C.	Symbol	
		Signal word	Warning
		Hazard statement	H290
		Precautionary statements	P234; P390; P406

<sup>a</sup> See Part III, Section 37 of the UN *Manual of tests and criteria* for the test methods.




**B.19 Acute toxicity** (see 10.1 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b>	$LD_{50} \leq 5 \text{ mg/kg body mass (oral)}$ $LD_{50} \leq 50 \text{ mg/kg body mass (skin/dermal)}$ $LC_{50} \leq 100 \text{ ppm (gas)}$ $LC_{50} \leq 0,5 \text{ mg/L (vapour)}$ $LC_{50} \leq 0,05 \text{ mg/L (dust, mist)}$	Symbol	
		Signal word	Danger
		Hazard statement	<b>Oral:</b> H300 <b>Dermal:</b> H310 <b>Inhalation:</b> H330
		Precautionary statements	<b>Oral:</b> P264; P270; P301+P310; P321; P330; P405; P501  <b>Dermal:</b> P262; P264; P270; P280; P302+P350; P310; P322; P361; P363; P405; P501  <b>Inhalation:</b> P260; P271; P284; P304+P340; P310; P320; P403+P233; P405; P501


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### B.19 Acute toxicity *(continued)*

Hazard category	Criteria	Hazard communication elements	
<b>2</b>	$LD_{50} > 5$ and $\leq 50$ mg/kg body mass (oral) $LD_{50} > 50$ and $\leq 200$ mg/kg body mass (skin/dermal) $LC_{50} > 100$ and $\leq 500$ ppm (gas) $LC_{50} > 0,5$ and $\leq 2,0$ mg/L (vapour) $LC_{50} > 0,05$ and $\leq 0,5$ mg/L (dust, mist)	Symbol	
		Signal word	Danger
		Hazard statement	<b>Oral:</b> H300 <b>Dermal:</b> H310 <b>Inhalation:</b> H330
		Precautionary statements	<b>Oral:</b> P264; P270; P301+P310; P321; P330; P405; P501 <b>Dermal:</b> P262; P264; P270; P280; P302+P350; P310; P322; P361; P363; P405; P501 <b>Inhalation:</b> P260; P271; P284; P304+P340; P310; P320; P403+P233; P405; P501

**B.19 Acute toxicity** *(continued)*


Hazard category	Criteria	Hazard communication elements	
<b>3</b>	$LD_{50} > 50$ and $\leq 300$ mg/kg body mass (oral)  $LD_{50} > 200$ and $\leq 1\,000$ mg/kg body mass (skin/dermal)  $LC_{50} > 500$ and $\leq 2\,500$ ppm (gas)  $LC_{50} > 2,0$ and $\leq 10,0$ mg/L (vapour)  $LC_{50} > 0,5$ and $\leq 1,0$ mg/L (dust/mist)	Symbol	
		Signal word	Danger
		Hazard statement	<b>Oral:</b> H301 <b>Dermal:</b> H311 <b>Inhalation:</b> H331
		Precautionary statements	<b>Oral:</b> P264; P270; P301+P310; P321; P330; P405; P501  <b>Dermal:</b> P280; P302+P352; P312; P322; P361; P363; P405; P501  <b>Inhalation:</b> P261; P271; P304+P340; P311; P321; P403+P233; P405; P501

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### B.19 Acute toxicity (concluded)

Hazard category	Criteria	Hazard communication elements	
<b>4</b>	$LD_{50} > 300$ and $\leq 2\,000$ mg/kg body mass (oral) $LD_{50} > 1\,000$ and $\leq 2\,000$ mg/kg body mass (skin/dermal) $LC_{50} > 2\,500$ and $\leq$ than 5 000 ppm (gas) $LC_{50} > 10,0$ and $\leq 20,0$ mg/L (vapour) $LC_{50} > 1,0$ and $\leq 5,0$ mg/L (dust, mist)	Symbol	
		Signal word	Warning
		Hazard statement	<b>Oral:</b> H302 <b>Dermal:</b> H312 <b>Inhalation:</b> H332
		Precautionary statements	<b>Oral:</b> P264; P270; P301+P312; P330; P501  <b>Dermal:</b> P280; P302+P352; P312; P322; P363; P501  <b>Inhalation:</b> P261; P271; P304+P340; P312
<b>5</b>	$LD_{50}$ between 2 000 mg/kg and 5 000 mg/kg body mass (oral or skin/dermal)  For gases, vapours, dusts, mists, an $LC_{50}$ in the equivalent range of the oral and dermal $LD_{50}$ (i.e. between 2 000 mg/kg and 5 000 mg/kg body mass).  See also the additional criteria <ul style="list-style-type: none"> <li>• Indication of significant effect in humans</li> <li>• Any mortality at category 4</li> <li>• Significant clinical signs at category 4</li> <li>• Indication from other studies.</li> </ul>	Symbol	None
		Signal word	Warning
		Hazard statement	<b>Oral:</b> H303 <b>Dermal:</b> H313 <b>Inhalation:</b> H333
		Precautionary statement	<b>Oral:</b> P312 <b>Dermal:</b> P312 <b>Inhalation:</b> P304+P312

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## B.20 Skin corrosion/irritation (see 10.2 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b> <b>Corrosive<sup>a</sup></b>	1 <i>Substances and tested mixtures</i>	Symbol	
	a) Human experience shows irreversible damage to the skin;	Signal word	Danger
	b) Structure/activity or structure property relationship to a substance or mixture already classified as corrosive;	Hazard statement	H314
	c) pH extremes of $\leq 2$ and $\geq 11,5$ including acid/alkali reserve capacity;	Precautionary statements	P260; P264; P280; P301+P330+P331; P303+P361+P353; P363; P304+P340; P310; P321; P305+P351+P338; P405; P501
	d) Positive results in a valid and accepted <i>in vitro</i> skin corrosion test; or		
	e) Animal experience or test data indicate that the substance or mixture causes irreversible damage to the skin following exposure of up to 4 h.		
	2 <i>Data for a mixture are not available</i>		
	Use the bridging principles in 10.2.2.2.		
	3 <i>Data are available for all components of a mixture or only for some components (the bridging principles do not apply)</i>		
	a) The substances can be added (additivity approach) and the sum of the concentrations of corrosive substances in the mixture is $\geq 5$ % (see 10.2.2.3.2 and table 26); or		
	b) the substances in the mixture cannot be added (additivity approach does not apply, for example, for acids and bases) and the mixture contains $\geq 1$ % corrosive substance(s) (see 10.2.2.3.3 and table 27).		
<sup>a</sup> Sub-categories 1A, 1B and 1C are included (see flow chart 2 and 10.2.1.2).			

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### B.20 Skin corrosion/irritation (continued)

Hazard category	Criteria	Hazard communication elements	
<b>2 Irritant</b>	<p>1. <i>Substances and tested mixtures</i></p> <p>a) Human experience or data shows reversible damage to the skin following exposure of up to 4 h;</p> <p>b) Structure/activity or structure property relationship to a substance or mixture already classified as an irritant</p> <p>c) Positive results in a valid and accepted <i>in vitro</i> skin irritation test (see 5.2.2); or</p> <p>d) Animal experience or test data indicates that the substance/mixture causes reversible damage to the skin following exposure of up to 4 h, the mean value of <math>\geq 2,3 \leq 4,9</math> for erythema/eschar or for oedema, or inflammation that persists to the end of the observation period, in 2 of the 3 test animals (see table 25)</p> <p>2. <i>Data are not available for a mixture</i></p> <p>Use the bridging principles in 10.2.2.2</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>a) The substances in the mixture can be added (additivity approach) and the sum of concentrations of corrosive substances in the mixture is <math>\geq 1\%</math> but <math>&lt; 5\%</math>; the sum of irritant substances is <math>\geq 10\%</math>; or (10 x the concentrations of corrosive substances) + (the concentrations of irritant ingredients) is <math>\geq 10\%</math>; or</p> <p>b) The substances in the mixture cannot be added (additivity approach does not apply, for example for acids and bases) and the mixture contains <math>\geq 3\%</math> irritant substances (see 10.2.2.3.3)</p>	Symbol	
		Signal word	Warning
		Hazard statements	H315
		Precautionary statements	P264; P280; P302+P352; P321; P332+P313; P362


## B.20 Skin corrosion/irritation *(concluded)*

Hazard category	Criteria	Hazard communication elements	
<b>3 Mild irritant</b>	<p>1. <i>Substances and tested mixtures</i></p> <p>Animal experience or test data indicates that the substance/mixture causes reversible damage to the skin following exposure of up to 4 h with a mean value <math>\geq 1,5 &lt; 2,3</math> for erythema/eschar in 2 of the 3 test animals (see table 25).</p> <p>2. <i>Data are not available for a mixture</i></p> <p>Use the bridging principles in 10.2.2.2</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>a) The substances in the mixture can be added (additivity approach) and the sum of the concentrations of irritant substances in the mixture is <math>\geq 1 \%</math> but <math>&lt; 10 \%</math>;</p> <p>b) The substances in the mixture cannot be added (additivity approach does not apply, for example, for acids and bases) and the sum of the mild irritant substances is <math>\geq 10 \%</math>;</p> <p>c) The sum of (10 x the concentrations of corrosive substances) + (the concentrations of irritant substances) is <math>\geq 1 \%</math> but <math>&lt; 10 \%</math>; or</p> <p>d) The sum of (10 x the concentrations of corrosive substances) + (the concentrations of irritant substances) + (the concentrations of mild irritant substances) is <math>\geq 10 \%</math>.</p> <p>4. <i>The concentrations of a mixture cannot be added</i></p> <p>Classify as category 3 if the mixture contains <math>\geq 3 \%</math> of a category 3 ingredient.</p>	Symbol	None
		Signal word	Warning
		Hazard statement	H316
		Precautionary statements	P332+P313

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### B.21 Eye damage/eye irritation (see 10.3 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b> <b>Irreversible effects</b>	<p>1. <i>Substances and tested mixtures</i></p> <p>a) Classification as corrosive to skin;</p> <p>b) Human experience or data shows damage to the eye which do not fully reverse within 21 d;</p> <p>c) Structure/activity or structure property relationship to a substance or mixture already classified as corrosive;</p> <p>d) pH extremes of <math>\leq 2</math> and <math>\geq 11,5</math> including buffering capacity;</p> <p>e) Positive results in a valid and accepted in vitro test to assess serious damage to eyes (see 5.2.2); or</p> <p>f) Animal experience or test data that the substance or mixture produces either:</p> <p>1) effects that are not expected to reverse, or have not reversed, on the cornea, iris or conjunctiva in at least one test animal; or</p> <p>2) a response of corneal opacity <math>\geq 3</math> and/or iritis <math>&gt; 1,5</math> in at least 2 of the 3 test animals (see 10.3.1.7)</p> <p>2. <i>Data are not available for a mixture</i></p> <p>Use the bridging principles in 10.3.2.2.</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>a) The substances in the mixture can be added (additivity approach) and the sum of the concentrations of substances classified as corrosive to skin and/or eyes category 1 substances in the mixture is <math>\geq 3\%</math>; or</p> <p>b) the substances in the mixture cannot be added (additivity approach does not apply, for example, acids and bases) and the mixture contains <math>\geq 1\%</math> of a corrosive substance (see 10.3.2.3.4(a))</p>	Symbol	
		Signal word	Danger
		Hazard statement	H318
		Precautionary statements	P280; P305+P351+P338; P310



## B.21 Eye damage/eye irritation (continued)

Hazard category	Criteria	Hazard communication elements	
<b>2A</b> <b>Irritant</b>	1. <i>Substances and tested mixtures</i>  Classify as a severe skin irritant if:	Symbol	
		Signal word	Warning
	a) Human experience or data shows changes in the eye that are fully reversible within 21 d;	Hazard statement	H319
	b) Structure/activity or structure property relationship to a substance or mixture already classified as an eye irritant; c) Positive results in a valid and accepted <i>in vitro</i> eye irritation test (see 5.3.2); or d) Animal experience indicates, or test data show, a response of corneal opacity $\geq 1$ , iritis $\geq 1$ or conjunctival oedema (chemosis) $\geq 2$ in at least 2 of the 3 test animals (see table 29)  2. <i>Data are not available for a mixture</i>  Use the bridging principles in 10.3.2.2.  3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i>  Classify as an irritant of hazard category 2A if:  a) The substances in the mixture can be added (additivity approach) and the sum of the concentrations of  1) skin and/or eye hazard category 1 substances in the mixture is $\geq 1\%$ but $< 3\%$ , or  2) eye irritation substances is $\geq 10\%$ , or  3) (10 x the concentrations of skin and/or eye hazard category 1 substances) + (the concentrations of eye irritants) is $\geq 10\%$ ; or  b) The substance in the mixture cannot be added (additivity approach does not apply, for example for acids and bases), and the sum of the concentrations of eye irritant substances is $\geq 3\%$ (see 10.3.2.3.4 (b)).	Precautionary statements	P264; P280; P305+P351+P338; P337+P313


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### B.21 Eye damage/eye irritation (*concluded*)

Hazard category	Criteria	Hazard communication elements	
<b>2B</b>  <b>Mild irritant</b>	<p>1. <i>Substances and tested mixtures</i></p> <p>a) Human experience or data show mild eye irritation</p> <p>b) Animal experience or test data indicates that the lesions are fully reversible within 7 d (see table 29)</p> <p>2. <i>Data are not available for a mixture</i></p> <p>Use the bridging principles in 10.3.2.2</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>a) The substances in the mixture can be added (additivity approach) and the sum of the concentrations of</p> <p>1) skin and/or eye hazard category 1 substances in the mixture is <math>\geq 1\%</math> but <math>&lt; 3\%</math>,</p> <p>2) eye irritant substances is <math>\geq 10\%</math>, or</p> <p>3) (10 x the concentrations of skin and/or eye hazard category 1 substances) + (concentrations of eye irritants) is <math>\geq 10\%</math>; or</p> <p>b) The substances in the mixture cannot be added (additivity approach does not apply, for example, for acids and bases) and the sum of the concentrations of eye irritant substances <math>\geq 3\%</math>.</p>	Symbol	None
		Signal word	Warning
		Hazard statement	H320
		Precautionary statements	P264; P305+P351+P338; P337+P313


## B.22 Respiratory sensitizer (see 10.4.1 for details)

Hazard category	Criteria	Hazard communication element	
1	<p>1 <i>Substances and tested mixtures</i></p> <p>a) Human evidence shows that the individual substance induces specific respiratory hypersensitivity, and/or</p> <p>b) positive results are obtained from an appropriate animal test.</p> <p>2 <i>Data for a mixture are not available</i></p> <p>Use the bridging principles (see 10.4.3.2) through one of the following:</p> <p>a) dilution;</p> <p>b) batching; or</p> <p>c) substantially similar mixture.</p> <p>3 <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>The concentration of any individual respiratory sensitizer in the mixture is:</p> <p>a) <math>\geq 1,0</math> % (solid/liquid); or</p> <p>b) <math>\geq 0,2</math> % (gas).</p>	Symbol	
		Signal word	Danger
		Hazard statement	H334
		Precautionary statements	P261; P285; P304+P341; P342+P311; P501

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### B.23 Skin sensitizer (see 10.4.2 for details)

Hazard category	Criteria	Hazard communication element	
1	<p>1 <i>Substances and tested mixtures</i></p> <p>a) Human evidence shows that an individual substance can induce sensitization by skin contact in a substantial number of persons, or</p> <p>b) positive results are obtained from an appropriate animal test.</p>	Symbol	
		Signal word	Warning
		Hazard statement	H317
	<p>2 <i>Data for a mixture are not available</i></p> <p>Use the bridging principles (see 10.4.3.2) through one of the following:</p> <p>a) dilution;</p> <p>b) batching; or</p> <p>c) substantially similar mixture.</p> <p>3 <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>The concentration of any individual skin sensitizer in the mixture has a concentration <math>\geq 1,0</math> % (solid/liquid/gas).</p>	Precautionary statements	P261; P272; P280; P302+P352; P333+P313; P321; P363; P501

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**B.24 Germ cell mutagenicity** (see 10.5 for details)



Hazard category	Criteria	Hazard communication elements	
<b>1</b> (both 1A and 1B)	a) Known to induce heritable mutations or regarded as if it induces heritable mutations in the germ cells of humans (see 10.5.2); or b) mixture contains $\geq 0,1$ % of germ cell mutagenic substances.	Symbol	
		Signal word	Danger
		Hazard statement	H340
		Precautionary statements	P201; P202; P281; P308+P313; P405; P501
<b>2</b>	a) Causes concern owing to the possibility that it may induce heritable mutations in the germ cells of humans (see 10.5.2); or b) mixture contains $\geq 1,0$ % of germ cell mutagenic substances.	Symbol	
		Signal word	Warning
		Hazard statement	H341
		Precautionary statements	P201; P202; P281; P308+P313; P405; P501

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### B.25 Carcinogenicity (see 10.6 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b> (both 1A and 1B)	Known or presumed human carcinogen, including mixtures containing $\geq 0,1$ % of such a substance.	Symbol	
		Signal word	Danger
		Hazard statement	H350
		Precautionary statements	P201; P202; P281; P308+P313; P405; P501
<b>2</b>	Suspected human carcinogen, including mixtures containing $\geq 0,1$ % or $\geq 1,0$ % of such a substance (see Notes (a) and (b) to table 39).	Symbol	
		Signal word	Warning
		Hazard statement	H351
		Precautionary statements	P201; P202; P281; P308+P313; P405; P501

**B.26(a) Toxic to reproduction** (see 10.7 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b> (both 1A and 1B)	a) Known or presumed human reproductive toxicant (see 10.7.2); or b) mixture contains $\geq 0,1\%$ or $\geq 0,3\%$ of such a substance (see 10.7.3 and Notes 1 and 2 to table 42).	Symbol	
		Signal word	Danger
		Hazard statement	H360
		Precautionary statements	P201; P202; P281; P308+P313; P405; P501
<b>2</b>	a) Suspected human reproductive toxicant (see 10.7.2); or b) mixture contains $\geq 0,1\%$ or $\geq 3,0\%$ of such a substance (see 10.7.3 and Notes 3 and 4 to table 42).	Symbol	
		Signal word	Warning
		Hazard statement	H361
		Precautionary statements	P201; P202; P281; P308+P313; P405; P501

**B.26(b) Effects on, or via, lactation** (see 10.7 for details)



Hazard category	Criteria	Hazard communication elements	
<b>Effects on, or via, lactation</b>	<p>1. <i>Substances and tested mixtures</i> Classify in this category if the substance or mixture causes concern for the health of breastfed children (see 10.7.2.3); or</p> <p>2. <i>Data for the complete mixture are not available</i> Apply the bridging principles</p> <p>3. <i>The bridging principles do not apply</i> Classify in this category if mixture contains <math>\geq 0,1\%</math> or <math>\geq 0,3\%</math> of at least one such a substance (see 10.7.3 and Notes 1 and 2 to table 42).</p>	Symbol	No symbol
		Signal word	No signal word
		Hazard statement	H362
		Precautionary statements	P201; P260; P263; P264; P270; P308+P313

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## B.27 Specific target organ toxicity – single exposure (see 10.8 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b>	<p>1) Reliable evidence on a substance or mixture (including the bridging principles) of an adverse effect on specific organ(s) in humans or animals.</p> <p>NOTE Use the guidance values for hazard category 1 (see 10.8.2.1.4 and table 45) as part of the weight of evidence evaluation.</p> <p>2) A mixture lacks sufficient data but contains:</p> <p>a) a hazard category 1 ingredient at a concentration <math>\geq 1,0</math> % but <math>&lt; 10,0</math> %; and/or</p> <p>b) an ingredient of hazard category 1 at a concentration <math>\geq 10,0</math> %.</p>	Symbol	
		Signal word	Danger
		Hazard statement	H370
		Precautionary statements	P260; P264; P270; P307+P311; P321; P405; P501
<b>2</b>	<p>1) Evidence on a substance or mixture (including the bridging principles) of an adverse effect on specific organ toxicity from animal studies or humans experience.</p> <p>NOTE Use the guidance values for hazard category 2 (see 10.8.2.1.4 and table 45) as part of the weight of evidence evaluation.</p> <p>2) A mixture lacks sufficient data, but contains:</p> <p>a) a hazard category 2 ingredient at a concentration <math>\geq 1</math> % but <math>&lt; 10</math> %; and/or</p> <p>b) a category 2 ingredient at a concentration <math>\geq 10</math> %.</p>	Symbol	
		Signal word	Warning
		Hazard statement	H371
		Precautionary statements	P260; P264; P270; P309+P311; P405; P501





## **B.27 Specific target organ toxicity – single exposure** *(concluded)*

Hazard category	Criteria	Hazard communication elements	
<b>3</b>	<p>a) <i>Respiratory tract irritation</i></p> <p>Evidence on the substance or mixture of transient irritant effects on respiratory tract in humans; or</p> <p>b) <i>Narcotic effects</i></p> <p>Evidence on the substance or mixture of transient narcotic effects from animal studies and in humans.</p>	Symbol	
		Signal word	Warning
		Hazard statement	H335 (respiratory tract irritation)  <b>or</b>  H336 (narcotic effects)
		Precautionary statements	P261; P271; P304+P340; P312; P403+P233; P405; P501

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### B.28 Specific target organ toxicity – repeated exposure (see 10.9 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b>	<p>a) Reliable evidence on a substance or mixture (including the bridging principles in 10.9.3.3) of an adverse effect on specific organ(s) in humans or animals.</p> <p>NOTE Use the guidance values for hazard category 1 (see table 49) as part of the weight of evidence evaluation.</p> <p>b) A mixture lacks sufficient data, but contains:</p> <p>1) a hazard category 1 ingredient at a concentration <math>\geq 1</math> % but <math>&lt; 10</math> % (see Note 1 to table 51); and/or</p> <p>2) a hazard category 1 ingredient at a concentration <math>\geq 10</math> % (see Note 2 to table 51)</p>	Symbol	
		Signal word	Danger
		Hazard statement	H372
		Precautionary statements	P260; P264; P270; P314; P501
<b>2</b>	<p>a) Evidence on a substance or a mixture (including the bridging principles in 10.9.3.3) of an adverse effect on specific organ toxicity from animal studies or human experience.</p> <p>NOTE Use the guidance values (see table 50) for hazard category 2 as part of the weight of evidence evaluation.</p> <p>b) A mixture lacks sufficient data, but contains:</p> <p>1) a hazard category 1 ingredient at a concentration <math>\geq 1,0</math> % but <math>&lt; 10</math> % (see Note 3 to table 51); and/or</p> <p>2) a hazard category 2 ingredient at a concentration <math>\geq 10</math> % (see Note 4 to table 51).</p>	Symbol	
		Signal word	Warning
		Hazard statement	H373
		Precautionary statements	P260; P314; P501

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**B.29 Aspiration hazard** (see 10.10 for details)


Hazard category	Criteria	Hazard communication elements	
<b>1</b>	<p>1. <i>Substances and tested mixtures</i></p> <p>a) Practical experience from reliable and good quality human evidence show human aspiration toxicity including chemical pneumonia, varying degree of pulmonary injury or death following aspiration; or</p> <p>b) hydrocarbons with a kinematic viscosity of 20,5 mm<sup>2</sup>/s or less, at 40 °C.</p>	Symbol	
		Signal word	Danger
		Hazard statement	H304
		Precautionary statements	P301+P310; P331; P405; P501
	<p>2. <i>Data for a mixture are not available</i></p> <p>Use the bridging principles given in 10.10.4.2.</p> <p>3. <i>Data are available for all components or only for some components (the bridging principles do not apply)</i></p> <p>a) The mixture contains 10 % or more of a substance or substances classified in hazard category 1 and has a kinematic viscosity of 20,5 mm<sup>2</sup>/s or less at 40 °C; or</p> <p>b) the mixture separates into two or more distinct layers, and one of the layers contains 10 % or more of a substance or substances classified in hazard category 1 of aspiration toxicity and has a kinematic viscosity of 20,5 mm<sup>2</sup>/s or less at 40 °C.</p>		

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### B.29 Aspiration hazard *(concluded)*

Hazard category	Criteria	Hazard communication elements	
<b>2</b>	<p>1. <i>Substances and tested mixtures</i></p> <p>Substances and mixtures, other than those classified in hazard category 1, that have a kinematic viscosity of 14 mm<sup>2</sup>/s or less at 40 °C and, on the basis of animal studies and expert judgement, are presumed to cause aspiration toxicity in humans.</p> <p>2. <i>Data for a mixture are not available</i></p> <p>Use the bridging principles given in 10.10.4.2.</p> <p>3. <i>Data are available for all components or only for some components (the bridging principles do not apply)</i></p> <p>a) The mixture has a kinematic viscosity of 14 mm<sup>2</sup>/s or less at 40 °C and contains 10 % or more of a substance or substances classified in hazard category 2;</p> <p>or</p> <p>b) the mixture has a kinematic viscosity of 14 mm<sup>2</sup>/s or less at 40 °C and separates into two or more distinct layers and one of the layers contains 10 % or more of a substance or substances classified in hazard category 2 of aspiration toxicity.</p>	Symbol	
		Signal word	Warning
		Hazard statement	H305
		Precautionary statements	P301+P310; P331; P405; P501

Amdt 1

**B.30 Acute hazards to the aquatic environment** (see clause 11 for details)

Hazard category	Criteria	Hazard communication elements	
<b>1</b>	<p>1. <i>Substances and tested mixtures:</i></p> <p><math>L(E)C_{50} \leq 1</math> mg/L, where</p> <p><math>LC_{50}</math> (fish), test period of 96 h,  <math>EC_{50}</math> (crustacea), test period of 48 h, or  <math>ErC_{50}</math> (algae or other aquatic plants), test period of 72 h or 96 h.</p> <p>2. <i>Data for a mixture are not available</i></p> <p>Use the bridging principles given in 11.3.3</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>a) <u>For mixtures containing classified ingredients</u></p> <p>The summation method (see 11.3.4.2) shows that [Concentration of Acute 1] <math>\times M &gt; 25</math> %.</p> <p>NOTE See table 60 for the relevant value of the multiplication factor <math>M</math>.</p> <p>b) <u>For mixtures containing tested ingredients</u></p> <p>The additivity formula (see 11.3.4.1.2) shows that <math>L(E)C_{50} \leq 1</math> mg/L.</p> <p>c) <u>For mixtures containing both classified and tested ingredients</u></p> <p>The combined additivity formula and summation method (see 11.3.4.1.2 and 11.3.4.2) show that [Concentration of Acute 1] <math>\times M &gt; 25</math> %</p> <p>NOTE See table 60 for the relevant value of the multiplication factor <math>M</math>.</p> <p>4. <i>Mixtures without any usable information for one or more relevant ingredients</i></p> <p>Use the available information and add the statement "x percent of the mixture consists of component(s) of unknown hazards to the aquatic environment".</p>	Symbol	
		Signal word	Warning
		Hazard statement	H400
		Precautionary statements	P273; P391; P501

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### B.30 Acute hazards to the aquatic environment *(continued)*

Hazard category	Criteria	Hazard communication elements	
<b>2</b>	<p>1. <i>Substances and tested mixtures:</i></p> <p><math>1 \text{ mg/L} &lt; L(E)C_{50} \leq 10 \text{ mg/L}</math>, where</p> <p><math>LC_{50}</math> (fish), test period of 96 h,  <math>EC_{50}</math> (crustacea), test period of 48 h, or  <math>ErC_{50}</math> (algae or other aquatic plants), test period of 72 h or 96 h.</p>	Symbol	None
		Signal word	None
		Hazard statement	H401
	<p>2. <i>Data for a mixture are not available</i></p> <p>Use the bridging principles given in 11.3.3</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>a) <u>For mixtures containing classified ingredients</u></p> <p>The summation method (see 11.3.4.2) shows that [(conc. of Acute 1 <math>\times</math> <math>M \times 10</math>) + (conc. of Acute 2)] &gt; 25 %.</p> <p>NOTE See table 60 for the relevant value of the multiplication factor <math>M</math>.</p> <p>b) <u>For mixtures containing tested ingredients</u></p> <p>The additivity formula (see 11.3.4.1.2) shows that <math>1 \text{ mg/L} &lt; L(E)C_{50} \leq 10 \text{ mg/L}</math>.</p> <p>c) <u>For mixtures containing both classified and tested ingredients</u></p> <p>The combined additivity formula and summation method (see 11.3.4.1.2 and 11.3.4.2) show that [(concentration of Acute 1 <math>\times</math> <math>M \times 10</math>) + (concentration of Acute 2)] &gt; 25 %</p> <p>NOTE See table 60 for the relevant value of the multiplication factor <math>M</math>.</p> <p>4. <i>Mixtures without any usable information for one or more relevant ingredients</i></p> <p>Use the available information and add the statement "x percent of the mixture consists of component(s) of unknown hazards to the aquatic environment".</p>	Precautionary statements	P273; 501

Amdt 1

### B.30 Acute hazards to the aquatic environment *(concluded)*


Hazard category	Criteria	Hazard communication elements	
<b>3</b>	<p><i>Substances and tested mixtures:</i></p> <p>10 mg/L &lt; <math>L(E)C_{50} \leq 100</math> mg/L, where</p> <p><math>LC_{50}</math> (fish), test period of 96 h,  <math>EC_{50}</math> (crustacea), test period of 48 h, or  <math>ErC_{50}</math> (algae or other aquatic plants), test period of 72 h or 96 h.</p> <p>2. <i>Data for a mixture are not available</i></p> <p>Use the bridging principles given in 11.3.3</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>a) <u>For mixtures containing classified ingredients</u></p> <p>The summation method (see 11.3.4.2) shows that [(conc. of Acute 1 × <math>M \times 100</math>) + (conc. of Acute 2) × 10) + (conc. of Acute 3)] &gt; 25 %.</p> <p>NOTE See table 60 for the relevant value of the multiplication factor <math>M</math>.</p> <p>b) <u>For mixtures containing tested ingredients</u></p> <p>The additivity formula (see 11.3.4.1.2) shows that 10 mg/L &lt; <math>L(E)C_{50} \leq 100</math> mg/L.</p> <p>c) <u>For mixtures containing both classified and tested ingredients</u></p> <p>The combined additivity formula and summation method (see 11.3.4.1.2 and 11.3.4.2) show that [(conc. of Acute 1 × <math>M \times 100</math>) + (conc. of Acute 2 × 10) + (conc. of Acute 3)] &gt; 25 %</p> <p>NOTE See table 60 for the relevant value of the multiplication factor <math>M</math>.</p> <p>4. <i>Mixtures without any usable information for one or more relevant ingredients</i></p> <p>Use the available information and add the statement "x percent of the mixture consists of component(s) of unknown hazards to the aquatic environment".</p>	Symbol	None
		Signal word	None
		Hazard statement	H402
		Precautionary statements	P273; P501

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### B.31 Chronic hazards to the aquatic environment (see clause 11 for details)

Hazard category	Criteria	Hazard communication elements	
1	<p>1. <i>Substances</i></p> <p>a) <math>L(E)C_{50} \leq 1</math> mg/L; and</p> <p>b) the substance lacks the potential to rapidly biodegrade and/or have the potential to bioaccumulate (<math>BCF \geq 500</math> or, if absent, <math>\log K_{ow} \geq 4</math>), and where</p> <p><math>LC_{50}</math> (fish), test period of 96 h,  <math>EC_{50}</math> (crustacea), test period of 48 h, or  <math>ErC_{50}</math> (algae or other aquatic plants), test period of 72 h or 96 h.</p> <p>2. <i>Mixtures</i></p> <p>Use the bridging principles given in 11.3.3.</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>[Conc. of Chronic 1] x <math>M &gt; 25</math> %</p> <p>NOTE See table 60 for the relevant value of the multiplication factor <math>M</math>.</p> <p>4. <i>Mixtures without any usable information for one or more relevant ingredients</i></p> <p>Use the available information and add the statement: "x percent of the mixture consists of component(s) of unknown hazards to the aquatic environment".</p>	Symbol	
		Signal word	Warning
		Hazard statement	H410
		Precautionary statements	P273; P391; P501

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### B.31 Chronic hazards to the aquatic environment *(continued)*

Hazard category	Criteria	Hazard communication elements	
<b>2</b>	<p>1. <i>Substances</i>:</p> <p>a) <math>1 \text{ mg/L} &lt; L(E)C_{50} \leq 10 \text{ mg/L}</math>; and</p> <p>b) the substance lacks the potential to rapidly biodegrade and/or have the potential to bioaccumulate (<math>BCF \geq 500</math> or if absent <math>\log K_{ow} \geq 4</math>); unless</p> <p>c) chronic NOECs <math>&gt; 1 \text{ mg/L}</math>, and where</p> <p style="padding-left: 40px;"><math>LC_{50}</math> (fish), test period of 96 h,  <math>EC_{50}</math> (crustacea), test period of 48 h, or  <math>ErC_{50}</math> (algae or other aquatic plants), test period of 72 h or 96 h.</p> <p>2. <i>Mixtures</i></p> <p>Use the bridging given in 11.3.3</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>[conc. of Chronic 1 <math>\times M \times 10</math>]  + [conc. of Chronic 2] <math>&gt; 25 \%</math></p> <p>NOTE See table 60 for the relevant value of the multiplication factor <math>M</math>.</p> <p>4. <i>For mixtures without any usable information for one or more relevant ingredients</i></p> <p>Use the available information and add the statement: "x percent of the mixture consists of component(s) of unknown hazards to the aquatic environment".</p>	Symbol	
		Signal word	None
		Hazard statement	H411
		Precautionary statements	P273; P391; P501

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### B.31 Chronic hazards to the aquatic environment *(continued)*

Hazard category	Criteria	Hazard communication elements	
<b>3</b>	<p>1. <i>Substances:</i></p> <p>a) <math>10 \text{ mg/L} &lt; L(E)C_{50} \leq 100 \text{ mg/L}</math>; and</p> <p>b) lack the potential to rapidly biodegrade and/or have the potential to bioaccumulate (<math>BCF \geq 500</math> or if absent <math>\log K_{ow} \geq 4</math>); unless</p> <p>c) chronic NOECs <math>&gt; 1 \text{ mg/L}</math>, and where</p> <p style="padding-left: 40px;"><math>LC_{50}</math> (fish), test period of 96 h,  <math>EC_{50}</math> (crustacea), test period of 48 h, or  <math>ErC_{50}</math> (algae or other aquatic plants), test period of 72 h or 96 h.</p> <p>2. <i>Mixtures</i></p> <p>Use the bridging principles given in 11.3.3.</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>[Conc. of Chronic 1 <math>\times M \times 100</math>]  + [Conc. of Chronic 2 <math>\times 10</math>]  + [Conc. of Chronic 3] <math>&gt; 25 \%</math></p> <p>NOTE See table 60 for the relevant value of the multiplication factor <math>M</math>.</p> <p>4. <i>Mixtures without any usable information for one or more relevant ingredients</i></p> <p>Use the available information and add the statement: "x percent of the mixture consists of component(s) of unknown hazards to the aquatic environment".</p>	Symbol	None
		Signal word	None
		Hazard statement	H412
		Precautionary statements	P273; P501

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### B.31 Chronic hazards to the aquatic environment *(concluded)*

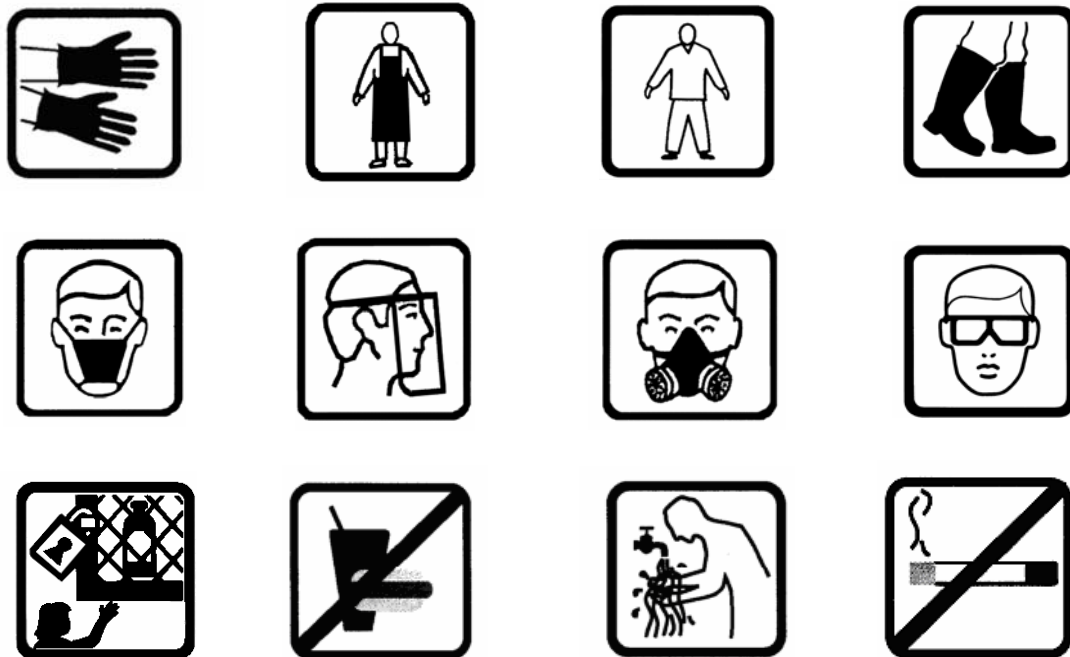
Hazard category	Criteria	Hazard communication elements	
<b>4</b>	<p>1. <i>Substances</i></p> <p>a) Poorly soluble and no acute toxicity is observed up the water solubility; and</p> <p>b) lacks the potential to rapidly biodegrade and the potential to bioaccumulate (BCF <math>\geq 500</math> or if absent <math>\log K_{ow} \geq 4</math>); unless</p> <p>c) chronic NOECs &gt; 1 mg/L.</p> <p>2. <i>Mixtures</i></p> <p>Use the bridging principles given in 11.3.3.</p> <p>3. <i>Data are available for all components of a mixture or for only some components (the bridging principles do not apply)</i></p> <p>Sum of the concentrations of components classified as Chronic 1, 2, 3 or 4 &gt; 25 %.</p> <p>4. <i>Mixtures without any usable information for one or more relevant ingredients</i></p> <p>Use the available information and add the statement: "x percent of the mixture consists of component(s) of unknown hazards to the aquatic environment".</p>	Symbol	None
		Signal word	None
		Hazard statement	H413
		Precautionary statements	P273; P501

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### B.32 Precautionary pictograms



# **ANNEX C**

## **GUIDANCE ON THE PREPARATION OF SAFETY DATA SHEETS (SDS)**

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## **Annex C**

(informative)

### **Guidance on the preparation of safety data sheets (SDS)**

#### **C.1 Introduction**

**C.1.1** This annex provides guidance on the preparation of an SDS under the requirements of the Globally Harmonized System of classification and labelling of chemicals (GHS). SDSs are an important element of hazard communication in the GHS, as explained in clause 8. Use of this guidance document should support compliance with the competent authority (CA) requirements and should allow the SDS to be prepared in accordance with the GHS.

NOTE In a South African context, the National Department of Labour is the CA for SDSs.

**C.1.2** The use of this guidance document is dependent on importing countries requirements for SDSs.

**C.1.3** Unless otherwise stated, all clauses and tables referred to in this annex can be found in the main text.

#### **C.2 General guidance for compiling an SDS**

##### **C.2.1 Scope and application**

SDSs should be produced for all substances and mixtures which meet the harmonized criteria for physical, health or environmental hazards under the GHS and for all mixtures that contain substances that meet the criteria for carcinogenic, toxic to reproduction or target organ systemic toxicity in concentrations exceeding the cut-off limits for SDS specified by the criteria for mixtures (see table 2). The CA could require SDSs for mixtures not meeting the criteria for classification as hazardous but which contain hazardous substances in certain concentrations. The CA may also require SDSs for substances or mixtures that meet the criteria for classification as hazardous for non-GHS classes/end-points. An SDS is a well-accepted and effective method for the provision of information, and could be used to convey information for substances or mixtures that do not meet, or are not included in the GHS classification criteria.

##### **C.2.2 General guidance**

**C.2.2.1** The writer of an SDS needs to keep in mind that an SDS must inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or mixture. An SDS contains information on the potential health effects of exposure and how to work safely with the substance or mixture. It also contains hazard information derived from physicochemical properties or environmental effects, on the use, storage, handling and emergency response measures related to that substance or mixture. The purpose of this annex is to ensure consistency and accuracy in the content of each of the mandatory headings required under GHS, so that the resulting SDS enables users to take the necessary measures relating to protection of health and safety at the workplace, and the protection of the environment. The information in an SDS should be written in a clear and concise manner. The SDS should be prepared by a competent person who takes into account the specific needs of the user audience, as far as it is known. Suppliers, manufacturers, importers or distributors placing substances and mixtures on the market should ensure that persons identified as being competent to prepare SDSs regularly attend refresher courses and training on the preparation of SDSs.

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**C.2.2.2** When writing an SDS, information should be presented in a consistent and complete form, with the workplace audience firmly in mind. However, it should be considered that all, or part of the SDS can be used to inform workers, employers, health and safety professionals, emergency personnel, relevant government agencies, as well as members of the community.

**C.2.2.3** Language used in the SDS should be simple, clear and precise, avoiding jargon, acronyms and abbreviations. Vague and misleading expressions should not be used. Phrases such as “may be dangerous”, “no health effects”, “safe under most conditions of use”, or “harmless” are also not recommended. It may be that information on certain properties is of no significance or that it is technically impossible to provide. If so, the reasons for this must be clearly stated under each heading. If it is stated that a particular hazard does not exist, the safety data sheet should clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available.

**C.2.2.4** The date of issue of the SDS should be stated and be very apparent. The date of issue is the date the SDS version was made public. This generally occurs shortly after the SDS authoring and publishing process is completed. Revised SDSs should clearly state the date of issue as well as a version number, revision number, supersedes date or some other indication of what version is replaced.

## **C.3 SDS format**

### **C.3.1 General**

**C.3.1.1** The information in the SDS should be presented using the following 16 headings in the order given below (see also 8.2):

1. Identification
2. Hazard identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

**C.3.1.2** An SDS is not a fixed length document. The length of the SDS should be commensurate with the hazard of the material and the information available.

**C.3.1.3** All pages of an SDS should be numbered and some indication of the end of the SDS should be given, for example “page 1 of 3”. Alternatively, each page should be numbered and it should be indicated whether there is a page following, for example “Continued on next page” or “End of SDS”.



## **C.3.2 SDS content**

### **C.3.2.1 General information on SDS content can be found in 8.3.**

**C.3.2.2** The minimum information outlined in table 3 shall be included on the SDS, where applicable and available, under the relevant headings. When information is unavailable, or lacking, this should be clearly stated on the SDS. The SDS should not contain any blanks.

**C.3.2.3** In addition, an SDS should contain a brief summary/conclusion of the data given, making it easy even for non-experts in the field to identify all the hazards for the hazardous substance/mixture.

**C.3.2.4** Use of abbreviations is not recommended because they may lead to confusion or decreased understanding.

## **C.3.3 Other information requirements**

**C.3.3.1** The minimum information requirements for an SDS are outlined in C.4 (see also C.3.2.2).

**C.3.3.2** In addition to the minimum information requirements, an SDS may also contain “additional information”. Where a material has additional relevant and available information about its nature and/or use, that information should be included in the SDS (see C.4.17).

## **C.3.4 Units**

Numbers and quantities should be expressed in units appropriate to the region into which the product is being supplied. In general, the International System of Units (SI) should be used.

## **C.4 Information requirements for the preparation of SDSs**

### **C.4.1 General**

This section describes the GHS information requirements for SDSs. A CA could require additional information (see C.4.17).

### **C.4.2 SECTION 1 — Identification**

#### **C.4.2.1 General**

Identify the substance or mixture and provide the name of the supplier, recommended uses and the contact detail information of the supplier including an emergency contact in this section.

#### **C.4.2.2 GHS product identifier**

In addition, or as an alternative to the GHS product identifier, the identity of the substance or mixture (GHS product identifier) should be exactly as found on the label. If one generic SDS is used to cover several minor variants of a substance or mixture, all names and variants should be listed on the SDS or the SDS should clearly delineate the range of substances included.

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### **C.4.2.3 Other means of identification**

It is permissible to identify a substance or mixture by alternative names, numbers, company product codes, or other unique identifiers. Provide other names or synonyms by which the substance or mixture is labelled or commonly known, if applicable.

### **C.4.2.4 Recommended use of the chemical and restrictions on use**

Provide the recommended or intended use of the substance or mixture, including a brief description of what it actually does, for example, flame retardant and anti-oxidant. State the restrictions on the use of the chemical as far as possible, including non-statutory recommendations by the supplier.

### **C.4.2.5 Supplier's details**

The name, full address and phone number(s) of the supplier should be included on the SDS.

### **C.4.2.6 Emergency phone number**

References to emergency information services should be included in all SDSs. If any restrictions apply, such as hours of operation (for example Monday - Friday, 8:00 a.m. - 6:00 p.m., or 24 hours) or limits on specific types of information (for example medical emergencies, or transportation emergencies), this should be clearly stated.

## **C.4.3 SECTION 2 — Hazard identification**

### **C.4.3.1 General**

This section describes the hazards of the substance or mixture and the appropriate warning information (signal word, hazard statement(s) and precautionary statement(s)) associated with those hazards. The section should include a brief summary/conclusion of the data given as described in C.3.3.2.

### **C.4.3.2 Classification of the substance or mixture**

**C.4.3.2.1** This sub-section indicates the hazard classification of the substance or mixture.

**C.4.3.2.2** If the substance or mixture is classified in accordance with clause 9, clause 10 and/or clause 11 of the GHS, provide the appropriate hazard class and hazard category to indicate the hazard, for example "flammable liquid, hazard category 1".

### **C.4.3.3 GHS label elements, including precautionary statements**

**C.4.3.3.1** Based on the classification, provide the appropriate labelling elements: signal word(s), hazard statement(s) and precautionary statement(s).

**C.4.3.3.2** Pictograms (hazard symbols) may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol, for example flame, skull and crossbones.

### **C.4.3.4 Other hazards that do not result in classification**

Provide information on other hazards that do not result in classification but may contribute to the overall hazards of the material, for example formation of air contaminants during hardening or processing, dust explosion hazards, suffocation, freezing or environmental effects such as hazards to soil-dwelling organisms.

## **C.4.4 SECTION 3 — Composition/information on ingredients**

### **C.4.4.1 General**

Identify the ingredient(s) of the product in this section. This includes identifying impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance. This section may also be used to provide information on complex substances.

NOTE For information on ingredients, the competent authority rules for Confidential Business Information (CBI) take priority over the rules for product identification. When applicable, indicate that confidential information about the composition was omitted.

### **C.4.4.2 Substances**

#### **C.4.4.2.1 Chemical identity of the substance**

The identity of a substance is provided by its common chemical name. The chemical name can be identical to the GHS product identifier.

NOTE The “common chemical name” may, for example, be the CAS name or IUPAC name, as applicable.

#### **C.4.4.2.2 Common name(s), synonym(s) of the substance**

Common names and synonyms should be provided where appropriate.

#### **C.4.4.2.3 CAS number and other unique identifiers for the substance**

The Chemical Abstract Service (CAS) Registry Number provides a unique chemical identification and should be provided when available. Other unique identifiers specific to a country or region, such as the European Community (EC) number could be added.

#### **C.4.4.2.4 Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance**

Identify any impurities and/or stabilizing additives, which are classified and which contribute to the classification of the substance.

### **C.4.4.3 Mixtures**

**C.4.4.3.1** For a mixture, provide the chemical identity, identification number (see C.4.4.2.3) and concentration or concentration ranges of all hazardous ingredients, which are hazardous to health or the environment within the meaning of the GHS, and are present above their cut-off levels. Manufacturers or suppliers may choose to list all ingredients, including non-hazardous ingredients.

#### **C.4.4.3.2 The concentrations of the ingredients of a mixture should be described as:**

- a) exact percentages in descending order by mass or volume; or
- b) ranges of percentages in descending order by mass or volume if such ranges are acceptable to the appropriate competent national authority.

**C.4.4.3.3** When using a proportion range, the health and environmental hazard effects should describe the effects of the highest concentration of each ingredient, provided that the effects of the mixture as a whole are not available.

NOTE The “proportion range” refers to the concentration or percentage range of the ingredient in the mixture.

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### **C.4.5 SECTION 4 — First-aid measures**

#### **C.4.5.1 General**

This section describes the initial care that can be given by an untrained responder without the use of sophisticated equipment and without a wide selection of medications available. If medical attention is required, the instructions should state this, including its urgency. It may be useful to provide information on the immediate effects, by route of exposure, and indicate the immediate treatment, followed by possible delayed effects with specific medical surveillance required.

#### **C.4.5.2 Description of necessary first-aid measures**

**C.4.5.2.1** Provide first-aid instructions by relevant routes of exposure. Use subheadings to indicate the procedure for each route (for example inhalation, skin, eye and ingestion). Describe expected immediate and delayed symptoms.

**C.4.5.2.2** Provide advice whether

- a) immediate medical attention is required and if delayed effects can be expected after exposure,
- b) the exposed individual should be moved from the area to fresh air,
- c) contaminated clothing should be removed from the exposed individual, and
- d) personal protective equipment (PPE) is recommended for first-aid responders.

#### **C.4.5.3 Most important symptoms/effects, acute and delayed**

Provide information on the most important symptoms/effects, acute and delayed, from exposure.

#### **C.4.5.4 Indication of immediate medical attention and special treatment needed, if necessary**

Where appropriate, provide information on clinical testing and medical monitoring for delayed effects, specific details on antidotes (where they are known) and contraindications.

### **C.4.6 SECTION 5 — Fire-fighting measures**

#### **C.4.6.1 General**

This section covers the requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

#### **C.4.6.2 Suitable extinguishing media**

Provide information on the appropriate type of extinguishers or fire-fighting agents. In addition, indicate whether any extinguishers are inappropriate for a particular situation involving the substance or mixture.

#### **C.4.6.3 Specific hazards arising from the chemical**

Provide advice on specific hazards that might arise from the chemical, such as hazardous combustion products that form when the substance or mixture burns. For example:

- a) “may produce toxic fumes of carbon monoxide if burning”; or
- b) “produces oxides of sulphur and nitrogen on combustion”.

#### **C.4.6.4 Special protective equipment and precautions for fire fighters**

**C.4.6.4.1** Provide advice on any precaution to be taken during fire-fighting, for example “keep containers cool with water spray”.

**C.4.6.4.2** Provide advice on appropriate protective equipment for fire-fighters, e.g. boots, overalls, gloves, eye and face protection and breathing apparatus.

### **C.4.7 SECTION 6 — Accidental release measures**

#### **C.4.7.1 General**

This section recommends the appropriate response to spills, leaks, or releases in order to prevent or minimize the adverse effects on persons, property and the environment in this section. Distinguish between responses for large and small spills where the spill volume has a significant impact on the hazard. The procedures for containment and recovery may indicate that different practices are required.

#### **C.4.7.2 Personal precautions, protective equipment and emergency procedures**

Provide advice related to accidental spills and release of the substance or mixture such as:

- a) the wearing of suitable protective equipment (including personal protective equipment, see section 8 of the SDS) to prevent any contamination of skin, eyes and personal clothing;
- b) removal of ignition sources and provision of sufficient ventilation; and
- c) emergency procedures such as the necessity to evacuate the danger area or to consult an expert.

#### **C.4.7.3 Environmental precautions**

Provide advice on any environmental precautions related to accidental spills and release of the substance or mixture, such as keeping away from drains, surface and ground water.

#### **C.4.7.4 Methods and materials for containment and cleaning up**

**C.4.7.4.1** Provide appropriate advice on how to contain and clean up a spill. Appropriate containment techniques may include

- a) bunding, covering of drains, and
- b) capping procedures.

**C.4.7.4.2** Appropriate clean up procedures may include

- a) neutralization techniques,
- b) decontamination techniques,

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- c) adsorbent materials,
- d) cleaning techniques,
- e) vacuuming techniques, and
- f) equipment required for containment/clean up (include the use of non-sparking tools and equipment where applicable).

**C.4.7.4.3** Provide any other issues relating to spills and releases, for example advice on inappropriate containment or clean up techniques.

### **C.4.8 SECTION 7 — Handling and storage**

#### **C.4.8.1 General**

This section provides guidance on safe handling practices that minimize the potential hazards to people, property and the environment from the substance or mixture. Emphasize precautions that are appropriate to the intended use and to the unique properties of the substance or mixture.

#### **C.4.8.2 Precautions for safe handling**

**C.4.8.2.1** Provide advice that

- a) allows safe handling of the substance or mixture,
- b) prevents handling of incompatible substances or mixtures, and
- c) minimizes the release of the substance or mixture to the environment.

**C.4.8.2.2** It is good practice to provide advice on general hygiene, such as

- a) “eating, drinking and smoking in work areas is prohibited”,
- b) “wash hands after use”, and
- c) “remove contaminated clothing and protective equipment before entering eating areas”.

#### **C.4.8.3 Conditions for safe storage, including any incompatibilities**

Ensure that the advice provided is consistent with the physical and chemical properties in section 9 – *Physical and chemical properties* of the SDS. If relevant, provide advice on specific storage requirements including:

- a) How to avoid
  - 1) explosive atmospheres,
  - 2) corrosive conditions,
  - 3) flammability hazards,
  - 4) incompatible substances or mixtures,

- 5) evaporative conditions, and
  - 6) potential ignition sources (including electrical equipment).
- b) How to control the effects of
- 1) weather conditions,
  - 2) ambient pressure,
  - 3) temperature,
  - 4) sunlight,
  - 5) humidity, and
  - 6) vibration.
- c) How to maintain the integrity of the substance or mixture by the use of
- 1) stabilizers, and
  - 2) anti-oxidants.
- d) Other advice including
- 1) ventilation requirements,
  - 2) specific designs for storage rooms/vessels,
  - 3) quantity limits under storage conditions (if relevant), and
  - 4) packaging compatibilities.

## **C.4.9 SECTION 8 — Exposure controls/personal protection**

### **C.4.9.1 General**

**C.4.9.1.1** Within this guidance the term “occupational exposure limit(s)” refers to limits in the air of the workplace (see foreword). In addition, “exposure control” means the full range of specific protection and prevention measures to be taken during use in order to minimize workers’ exposure and environmental exposure. Engineering control measures that are needed to minimize exposure to, and risks associated with the hazards of, the substance or mixture should be included in this section.

**C.4.9.1.2** Preventative and control measures are to be implemented in line with occupational health and safety legislation which requires the institution of a hierarchy of controls as follows: elimination of a source, substitution with a less hazardous chemical, isolation of the work area, using engineering controls, putting in place safe work practices and the use of personal protective equipment (PPE) as a last resort.

### **C.4.9.2 Control parameters**

**C.4.9.2.1** Where available, list the occupational exposure limits (limits in the air of the workplace or biological limit values), including notations, for a substance and for each of the ingredients of a mixture. If air contaminants are formed when using the substance or mixture as intended, available

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occupational exposure limits for these should also be listed. If an occupational exposure limit exists for the country or region in which the SDS is being supplied, this should be listed. The source of the occupational exposure limit should be stated on the SDS. When listing occupational exposure limits, use the chemical identity as specified in section 3 – *Composition/Information on ingredients* of the SDS.

**C.4.9.2.2** Where available, list the biological limit values, including notations, for a substance and for each of the ingredients of a mixture. Where possible, the biological limit value should be relevant to the countries or regions in which the SDS is being supplied. The source of the biological limit value should be stated on the SDS. When listing biological limit values, use the chemical identity as specified in section 3 of the SDS.

**C.4.9.2.3** Where a control banding approach is recommended for providing protection in relation to specific uses then sufficient detail should be given to enable effective management of the risk. The context and limitations of the specific control banding recommendation should be made clear.

### **C.4.9.3 Appropriate engineering controls**

The description of appropriate exposure control measures should relate to the intended modes of use of the substance or mixture. Sufficient information should be provided to enable a proper risk assessment to be carried out. Indicate when special engineering controls are necessary, and specify which type. Examples include:

- a) “maintain air concentrations below occupational exposure standards”, using engineering controls if necessary;
- b) “use local exhaust ventilation when...”;
- c) “use only in an enclosed system”;
- d) “use only in spray paint booth or enclosure”;
- e) “use mechanical handling to reduce human contact with materials”; or
- f) “use explosive dust handling controls”.

**NOTE** The information provided here should complement that provided under section 7 – *Handling and storage* of the SDS.

### **C.4.9.4 Individual protection measures, such as personal protective equipment (PPE)**

**C.4.9.4.1** The individual protection measures given on the SDS should be consistent with good occupational hygiene practices. Personal protective equipment (PPE) should be used in conjunction with other control measures, including engineering controls, ventilation, and isolation. See also section 5 – *Fire-fighting measures* of the SDS for specific fire/chemical PPE advice.

**C.4.9.4.2** Identify the PPE needed to minimize the potential for illness or injury due to exposure from the substance or mixture:

- a) Eye/face protection – specify the type of eye protection and/or face shield required, based on the hazard of the substance or mixture and potential for contact;
- b) Skin protection – specify the protective equipment to be worn (for example, type of gloves, boots, bodysuit) based on the hazards associated with the substance or mixture and the potential for contact;



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- c) Respiratory protection – specify appropriate types of respiratory protection based on the hazard and potential for exposure, including air-purifying respirators and the proper purifying element (cartridge or canister) or breathing apparatus; and
- d) Thermal hazards – when specifying protective equipment to be worn for materials that represent a thermal hazard, special consideration should be given to the construction of the PPE.

**C.4.9.4.3** Special requirements could exist for gloves or other protective clothing to prevent skin, eye or lung exposure. Clearly state the type of PPE, for instance “PVC gloves” or “nitrile rubber gloves”. The thickness and breakthrough time of the glove material should also be given. Special requirements might exist for respirators.

### **C.4.10 SECTION 9 — Physical and chemical properties**

**C.4.10.1** Describe the empirical data of the substance or mixture (if possible) in this section.

**C.4.10.2** In the case of a mixture, the entries should clearly indicate to which ingredient the data apply, unless it is valid for the whole mixture. The data included in this subsection should apply to the substance or mixture.

**C.4.10.3** Clearly identify the properties listed below and specify appropriate units of measure and/or reference conditions where applicable. If relevant for the interpretation of the numeric value, the method of test should also be provided, for example in the case of flash point, “closed-cup”.

- a) Appearance (physical state, colour etc).
- b) Odour.
- c) Odour threshold.
- d) pH.
- e) Melting point/freezing point.
- f) Initial boiling point and boiling range.
- g) Flash point.
- h) Evaporation rate.
- i) Flammability (solid, gas).
- j) Upper/lower flammability or explosive limits.
- k) Vapour pressure.
- l) Vapour density.
- m) Relative density.
- n) Solubility.
- o) Partition coefficient: n-octanol/water.
- p) Auto-ignition temperature.
- q) Decomposition temperature.
- r) Viscosity.

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If specific characteristics do not apply or are not available, they should still be listed on the SDS with a statement that they do not apply or are not available.

Other physical or chemical parameters in addition to those listed above may also be included in this section of the SDS.

### **C.4.11 SECTION 10 — Stability and reactivity**

#### **C.4.11.1 Reactivity**

**C.4.11.1.1** Describe the reactivity hazards of the substance or mixture in this section. Provide specific test data for the substance or mixture as a whole, where available. However, the information may also be based on general data for the class or family of chemical if such data adequately represent the anticipated hazard of the substance or mixture.

**C.4.11.1.2** If data for mixtures are not available, ingredient data should be provided. In determining incompatibility, consider the substances, containers, and contaminants that the substance or mixture might be exposed to during transportation, storage and use.

#### **C.4.11.2 Chemical stability**

Indicate if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Describe any stabilizers that are, or need to be, used to maintain the product. Indicate the safety significance of any change in the physical appearance of the product.

#### **C.4.11.3 Possibility of hazardous reactions**

If relevant, state if the substance or mixture will react or polymerize, releasing excess pressure or heat, or creating other hazardous conditions. Describe under what conditions the hazardous reactions may occur.

#### **C.4.11.4 Conditions to avoid**

List conditions such as heat, pressure, shock, static discharge, vibrations or other physical stresses that might result in a hazardous situation.

#### **C.4.11.5 Incompatible materials**

List the classes of chemicals or specific substances that react with the substance or mixture to produce a hazardous situation (for example, explosion, release of toxic or flammable materials and liberation of excessive heat).

#### **C.4.11.6 Hazardous decomposition products**

List known and reasonably anticipated hazardous decomposition products produced as a result of use, storage and heating. Hazardous combustion products should be included in section 5 – *Fire fighting measures* of the SDS.

## **C.4.12 SECTION 11 — Toxicological information**

### **C.4.12.1 General**

**C.4.12.1.1** This section is used primarily by medical professionals, occupational health and safety professionals and toxicologists. A concise but complete and comprehensible description of the various toxicological (health) effects, and the available data used to identify those effects, should be provided. Under GHS classification, the relevant hazards, for which data should be provided, are:

- a) acute toxicity (see 10.1);
- b) skin corrosion/irritation (see 10.2);
- c) serious eye damage/irritation (see 10.3);
- d) respiratory and skin sensitization (see 10.4);
- e) germ cell mutagenicity (see 10.5);
- f) carcinogenicity (see 10.6)
- g) reproductive toxicity (see 10.7);
- h) Specific target organ toxicity – Single exposure (see 10.8);
- i) Specific target organ toxicity – Repeated exposure (see 10.9); and
- j) aspiration hazards (see 10.10).

If data for any of these hazards are not available, they should still be listed on the SDS with a statement that data are not available.

**C.4.12.1.2** The data included in this section should apply to the substance or mixture as used. The toxicological data should describe the mixture. If that information is not available, the classification under GHS and the toxicological properties of the hazardous ingredients should be provided.

**C.4.12.1.3** The health effects included in the SDS should be consistent with those described in the studies used for the classification of the substance or mixture.

NOTE Test methods to determine the hazards to the aquatic environment are given in 11.1.4 to 11.1.8.

**C.4.12.1.4** General statements such as “Toxic” with no supporting data or “Safe if properly used” are not acceptable as they are misleading and do not provide a description of health effects. Phrases such as “not applicable”, “not relevant”, or leaving blank spaces in the health effects section can lead to confusion and misunderstanding and should not be used. For health effects where information is not available, this should be clearly stated. Health effects should be described accurately and relevant distinctions made, for example allergic contact dermatitis and irritant contact dermatitis should be distinguished from each other.

**C.4.12.1.5** Where there is a substantial amount of test data available on the substance or mixture, it might be desirable to summarize the results, for instance by route of exposure (see C.4.12.1).

**C.4.12.1.6** Also provide information on the relevant negative data (see C.2.2.3). Information to support negative test results should be provided (for example “carcinogenicity studies in the rat have shown no significant increase in the incidence of cancer”).

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### **C.4.12.2 Information on the likely routes of exposure**

Provide information on the likely routes of exposure and the effects of the substance or mixture via each possible route of exposure, that is, through ingestion (swallowing), inhalation or skin/eye exposure. A statement should be made if health effects are not known.

### **C.4.12.3 Symptoms related to the physical, chemical and toxicological characteristics**

Describe the potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products. Provide information on the symptoms related to the physical, chemical, and toxicological characteristics of the substance or mixture following exposure related to the intended uses. Describe the first symptoms at the lowest exposures through to the consequences of severe exposure, for example "headaches and dizziness may occur, proceeding to fainting or unconsciousness; large doses may result in coma and death".

### **C.4.12.4 Delayed and immediate effects and also chronic effects from short and long term exposure**

Provide information on whether delayed or immediate effects can be expected after short or long term exposure. Also provide information on acute and chronic health effects relating to human exposure to the substance or mixture. Where human data are not available, animal data should be summarised and the species clearly identified. It should be indicated in the SDS whether toxicological data is based on human or animal data.

### **C.4.12.5 Numerical measures of toxicity (such as acute toxicity estimates)**

Provide information on the dose, concentration or conditions of exposure that may cause adverse health effects. Where appropriate, doses should be linked to symptoms and effects, including the period of exposure likely to cause harm.

### **C.4.12.6 Interactive effects**

Information on interactions should be included if relevant and readily available.

### **C.4.12.7 Specific chemical data are not available**

It might not always be possible to obtain information on the hazards of a substance or mixture. In cases where data on the specific substance or mixture are not available, data on the chemical class, if appropriate, may be used. Where generic data are used or where data are not available, this should be stated clearly in the SDS.

### **C.4.12.8 Mixtures**

If a mixture has not been tested for its health effects as a whole, then information on each ingredient as given in C.4.4.3.1 should be provided and the mixture should be classified using the processes that are described in clause 5 and subsequent clauses.

### **C.4.12.9 Mixture versus ingredient information**

**C.4.12.9.1** Ingredients might interact with each other in the body resulting in different rates of absorption, metabolism and excretion. As a result, the toxic actions may be altered and the overall toxicity of the mixture may be different from its ingredients.

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**C.4.12.9.2** It is necessary to consider whether the concentration of each ingredient is sufficient to contribute to the overall health effects of the mixture. The information on toxic effects should be presented for each ingredient, except:

- a) if the information is duplicated, it is not necessary to list this more than once. For example, if two ingredients both cause vomiting and diarrhoea, it is not necessary to list this twice. Overall, the mixture is described as causing vomiting and diarrhoea;
- b) if it is unlikely that these effects will occur at the concentrations present. For example, when a mild irritant is diluted in a non-irritating solution, there comes a point where the overall mixture would be unlikely to cause irritation;
- c) predictions of the interactions between ingredients is extremely difficult, and where information on interactions is not available, assumptions should not be made. Instead, the health effects of each ingredient should be listed separately.

### **C.4.12.10 Other information**

Other relevant information on adverse health effects should be included even when not required by the GHS classification criteria.

## **C.4.13 SECTION 12 — Ecological information**

### **C.4.13.1 General**

**C.4.13.1.1** Provide information to evaluate the environmental impact of the substance or mixture if it were released to the environment. This information can assist in handling spills, and evaluating waste treatment practices and should clearly indicate species, media, units, test duration and test conditions. Where information is not available this should be stated. Provide also a short summary of the data given under C.4.13.2 to C.4.13.6.

NOTE References to test methods that can be used to determine the hazards to the aquatic environment are given in 11.1.4 to 11.1.8 (see also annex J).

**C.4.13.1.2** Some ecotoxicological properties are substance specific, that is, bioaccumulation, persistence and degradability. The information should therefore be given, where available and appropriate, for each substance of the mixture.

### **C.4.13.2 Toxicity**

Information on toxicity can be provided using data from tests performed on aquatic and/or terrestrial organisms. This should include relevant available data on both acute and chronic aquatic toxicity for fish, crustaceans, algae and other aquatic plants. In addition, toxicity data on other organisms (including soil micro-and macro-organisms) such as birds, bees and plants, should be included when available. Where the substance or preparation has inhibitory effects on the activity of micro-organisms, the possible impact on sewage treatment plants should be mentioned.

### **C.4.13.3 Persistence and degradability**

Persistence and degradability is the potential for the substance or the appropriate constituents of a mixture to degrade in the environment, either through biodegradation or other processes, such as oxidation or hydrolysis. Test results relevant to assess persistence and degradability should be given where available. If degradation half-lives are quoted it must be indicated whether these half-lives refer to mineralization or to primary degradation. The potential of the substance or certain constituents (see also C.4.13.5) of a mixture to degrade in sewage treatment plants should also be mentioned.

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### **C.4.13.4 Bioaccumulative potential**

Bioaccumulation is the potential for the substance or certain constituents of a mixture to accumulate in biota and, possibly, pass through the food chain. Test results relevant to assess the bioaccumulative potential should be given. This should include reference to the octanol-water partition coefficient ( $K_{ow}$ ) and bioconcentration factor (BCF), if available.

### **C.4.13.5 Mobility in soil**

Mobility in soil is the potential of a substance or the constituents of a mixture, if released to the environment, to move under natural forces to the groundwater or to a distance from the site of release. The potential for mobility in soil should be given where available. Information on mobility can be determined from relevant mobility data such as adsorption studies or leaching studies. For example,  $K_{ow}$  values can be predicted from octanol/water partition coefficients ( $K_{ow}$ ). Leaching and mobility can be predicted from models.

NOTE Where real data on the substance or mixture is available this data will take precedence over models and predictions.

### **C.4.13.6 Other adverse effects**

Information on any other adverse effects to the environment should be included where available, such as environmental fate (exposure), ozone depletion potential, photochemical ozone creation potential, endocrine disrupting potential and/or global warming potential.

## **C.4.14 SECTION 13 — Disposal considerations**

**C.4.14.1** Provide information for proper disposal, recycling or reclamation of the substance or mixture and/or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements of the national competent authority. For the safety of persons conducting disposal, recycling or reclamation activities, please refer to the information in section 8 – *Exposure controls/Personal protection* of the SDS.

**C.4.14.2** Specify disposal containers and methods.

**C.4.14.3** Discuss physical/chemical properties that may affect disposal options.

**C.4.14.4** Discourage sewage disposal.

**C.4.14.5** Where appropriate, identify any special precautions for incineration or landfill.

## **C.4.15 SECTION 14 — Transport information**

### **C.4.15.1 General**

This section provides basic classification information for the transporting/shipment of a hazardous substance or mixture by road, rail, sea or air. Where information is not available or relevant this should be stated.

#### **C.4.15.2 UN number**

Provide the UN number (the four-figure identification number of the substance or article) from SANS 10228.

#### **C.4.15.3 UN proper shipping name**

Provide the UN proper shipping name (see SANS 10228 and SANS 10229-1). For substances or mixtures the UN proper shipping name should be provided in this subsection if it has not appeared as the GHS product identifier or national or regional identifiers.

#### **C.4.15.4 Transport hazard class(es)**

Provide the transport class (and subsidiary risks) assigned to the substances or mixtures according to the most predominant hazard that they present in accordance with the *UN Model Regulations*<sup>4</sup>.

#### **C.4.15.5 Packing group, if applicable**

Provide the packing group number from SANS 10228, if applicable.

#### **C.4.15.6 Environmental hazards**

Indicate whether the substance or mixture is a known marine pollutant according to the IMDG Code, and if so, whether it is a “marine pollutant” or a “severe marine pollutant”. Also indicate whether the substance or mixture is environmentally hazardous.

#### **C.4.15.7 Special precautions for user**

Provide information on any special precautions, which a user needs to be aware of, or needs to comply with in connection with transport.

### **C.4.16 SECTION 15 — Regulatory information**

#### **C.4.16.1 General**

Describe any other regulatory information on the substance or mixture that is not provided elsewhere in the SDS (for example, whether the substance or mixture is subject to the Montreal Protocol, the Stockholm Convention or the Rotterdam Convention).

#### **C.4.16.2 Safety, health and environmental regulations specific for the product in question**

Provide relevant national and/or regional information on the regulatory status of the substance or mixture (including its ingredients) under relevant safety, health and environmental regulations. This should include whether the substance is subject to any prohibitions or restrictions in the country or region into which it is being supplied.

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### **C.4.17 SECTION 16 — Other information**

Provide information relevant to the preparation of the SDS in this section. This should incorporate other information that does not belong to sections 1 to 15 of the SDS, including information on the preparation and revision of the SDS such as:

- a) the date of preparation of the latest revision of the SDS. When revisions are made to an SDS, unless it has been indicated elsewhere, clearly indicate where the changes have been made to the previous version of the SDS. Suppliers should maintain an explanation of the changes and be willing to provide it upon request;
- b) a key/legend to abbreviations and acronyms used in the SDS; and
- c) key literature references and sources for data used to compile the SDS.



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# **ANNEX D**

## **CONSUMER PRODUCT LABELLING BASED ON THE LIKELIHOOD OF INJURY**

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## **Annex D**

(informative)

### **Consumer product labelling based on the likelihood of injury**

#### **D.1 Introduction**

**D.1.1** The Globally Harmonized System of classification and labelling of chemicals is based on an assessment of the intrinsic hazardous properties of the chemicals involved. However, it has been recognized that some systems provide information about chronic health hazards in consumer products only after considering additional data regarding potential exposures to consumers under normal conditions of use or foreseeable misuse. These systems thus provide information based on an assessment of risk, or the likelihood of injury occurring from exposure to these products. Where this exposure assessment and determination of likelihood of injury reveal that the potential for harm to occur as a result of the expected exposures is insignificant, chronic health hazards may not be included on the product label for consumer use. This type of system was recognized in a paper published by the IOMC *Description and further clarification of the anticipated application of the Globally Harmonized System (GHS)*, (reference IFCS/ISG3/98.32B)

*“The application of the components of the system may vary by type of product or stage of the life cycle. Once a chemical is classified, the likelihood of adverse effects may be considered in deciding what informational or other steps should be taken for a given product or use setting”.*

**D.1.2** The work on the GHS has not addressed harmonization of this type of approach. However, in recognition that it is an approach that has been used, and will continue to be used in the future, this annex is being provided to give additional guidance on how such an approach might work in practice.

**D.1.3** Exposure assessments for some consumer products are used to determine what information is included on a label in this type of approach. Regulators and manufacturers obtain exposure data or generate hypothetical exposure data based on customary use or foreseeable misuse. These assumptions are then used to determine whether a chronic health hazard is included on a consumer product label, and what precautions are to be followed, under a risk-based approach. These decisions are thus made on the basis of considerations regarding the likelihood of harm occurring in the consumer exposure situations that have been identified.

**D.1.4** Consumer product labels in some systems are based on a combination of hazard and risk. However, acute and physical hazards may be indicated on the label, while chronic health effects labelling based on risk is not indicated. This may be due in part to the expectation that exposures to some consumer products are of short duration, and thus may not be sufficient to lead to the development of chronic health effects as a result of those exposures. These expectations might not be accurate where consumer products are used in a workplace, e.g. paints or adhesives used by construction workers on a regular basis

**D.1.5** While intrinsic hazards of a chemical can be determined for all sectors, information about exposure, and thus risk, varies significantly among the sectors covered by the GHS. The vehicle by which this information is then transmitted to the user also varies. In some cases, particularly in the consumer setting, the label is the sole source of information, while in others, especially the workplace, it is one piece of a comprehensive system, supplemented by SDSs and worker training. In transport, a label transmits the primary information, but additional information is provided by the transport documentation.

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### **D.2 General principles**

**D.2.1** The specific risk assessment approach has not been addressed or harmonized in the GHS. However, certain general principles shall be taken into account as indicated in D.2.2 to D.2.4.

**D.2.2** All chemicals should be classified based on GHS classification criteria. The first step in risk assessment is the classification of a substance or a mixture by taking the intrinsic hazards into account, based on the GHS criteria, and communicating the information.

**D.2.3** The hazard classification should lead directly to labelling of acute health effects, environmental hazards and physical hazards. The labelling approach that involves a risk assessment should only be applied to chronic health hazards, for example carcinogenicity, reproductive toxicity, or target organ systemic toxicity based on repeated exposure. The only chemicals to which risk assessment may be applied to are those in the consumer product setting where consumer exposures are generally limited in quantity and duration.

**D.2.4** Estimates of possible exposures and risks to consumers should be based on conservative, protective assumptions in order to minimize the possibility of underestimating exposure or risk. The assessment of the risk and the approach to extrapolating animal data to humans should also involve a conservative margin of safety through establishment of uncertainty factors.

# **ANNEX E**

## **EXAMPLES OF ARRANGEMENTS OF THE GHS LABEL ELEMENTS**

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## **Annex E**

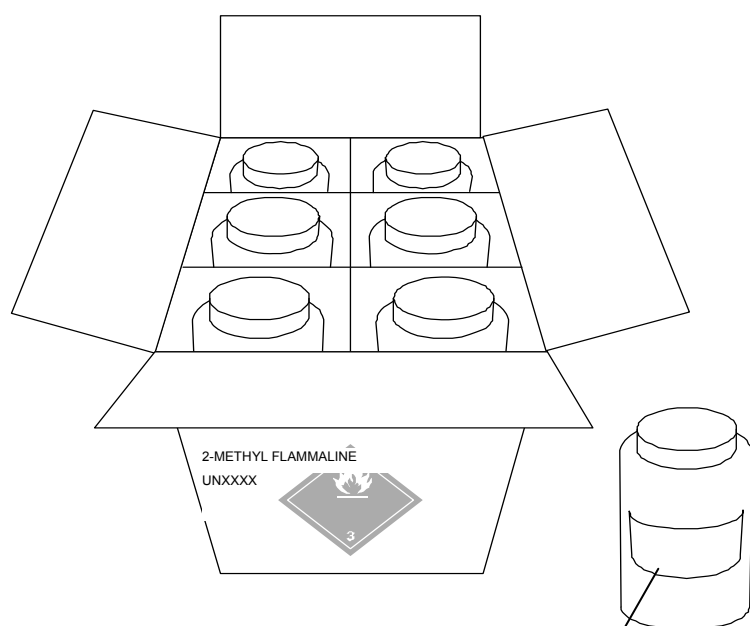
(informative)


### **Examples of arrangements of the GHS label elements**

#### **Example 1: Combination packaging for a category 2 flammable liquid**

**Outer packaging:** Box with the transport mark and label, and the flammable liquid hazard diamond in accordance with SANS 10229-1 or SANS 10233, as applicable.

**Inner packaging:** Plastics receptacles with the GHS hazard label



<b>2-METHYL FLAMMALINE</b>		<b>Product identifier</b> (see 6.7.2.4)
	<b>SIGNAL WORD</b> (see 6.7.2.1)	
	<b>Hazard statements</b> (see 6.7.2.2)	
<b>Precautionary statements</b> (see 6.7.2.3)		
<b>Supplier identification</b> (see 6.7.2.5)		

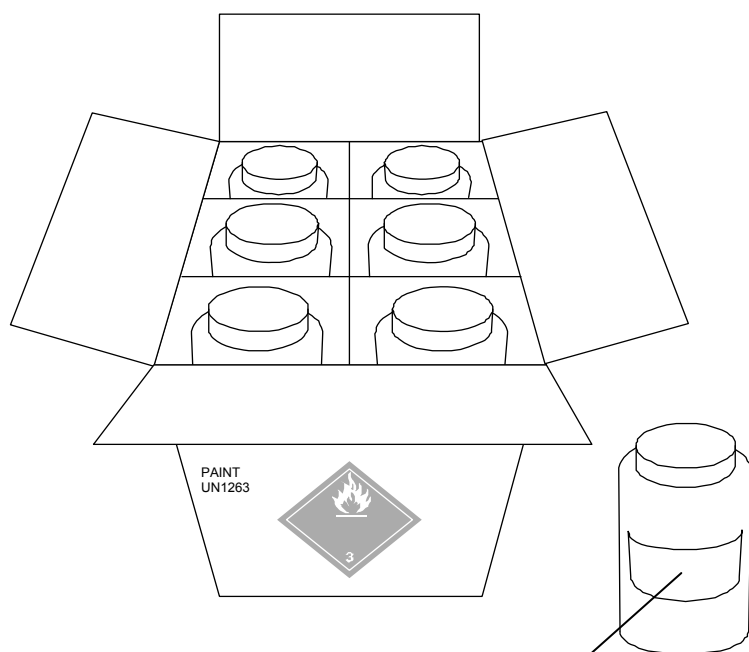
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### Example 2: Combination packaging for a substance that is a category 1 specific target organ toxicant and a category 2 flammable liquid

**Outer packaging:** Box with the transport mark and label, and the flammable liquid transport diamond in accordance with SANS 10229-1 or SANS 10233, as applicable.

**Inner packaging:** Plastics receptacles with the GHS hazard label.



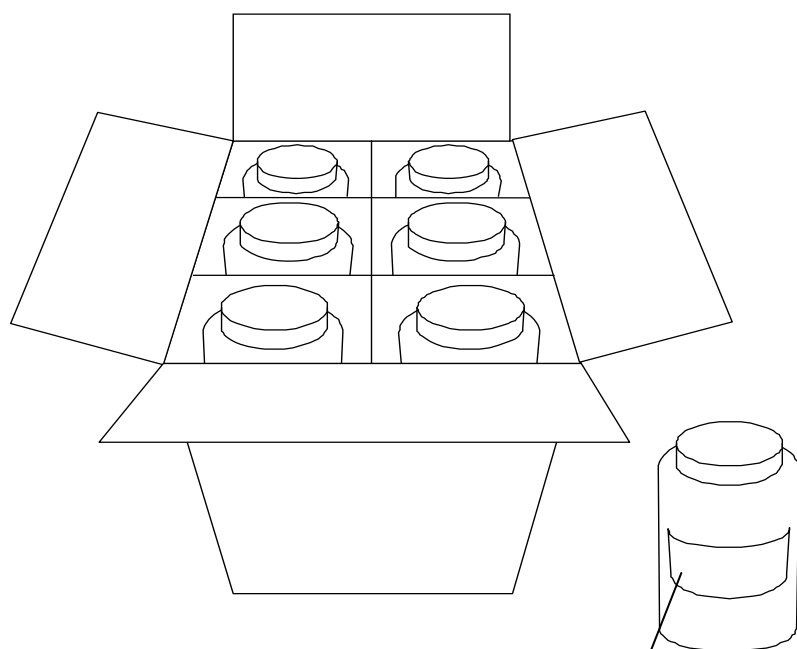
<b>PAINT (FLAMMALINE, LEAD CHROMOMIUM)</b>		<b>Product identifier</b> (see 6.7.2.4)
	<b>SIGNAL WORD</b> (see 6.7.2.1)	
	<b>Hazard statements</b> (see 6.7.2.2))	
<b>Precautionary statements</b> (see 6.7.2.3)		
<b>Supplier identification</b> (see 6.7.2.5)		




### **Example 3: Combination packaging for a substance that is a category 2 skin irritant and category 2A eye irritant**

**Outer packaging:** Box with no transport mark and label and no hazard class diamond. However, the GHS label shall be depicted.

**Inner packaging:** Plastics receptacles with the GHS hazard label.

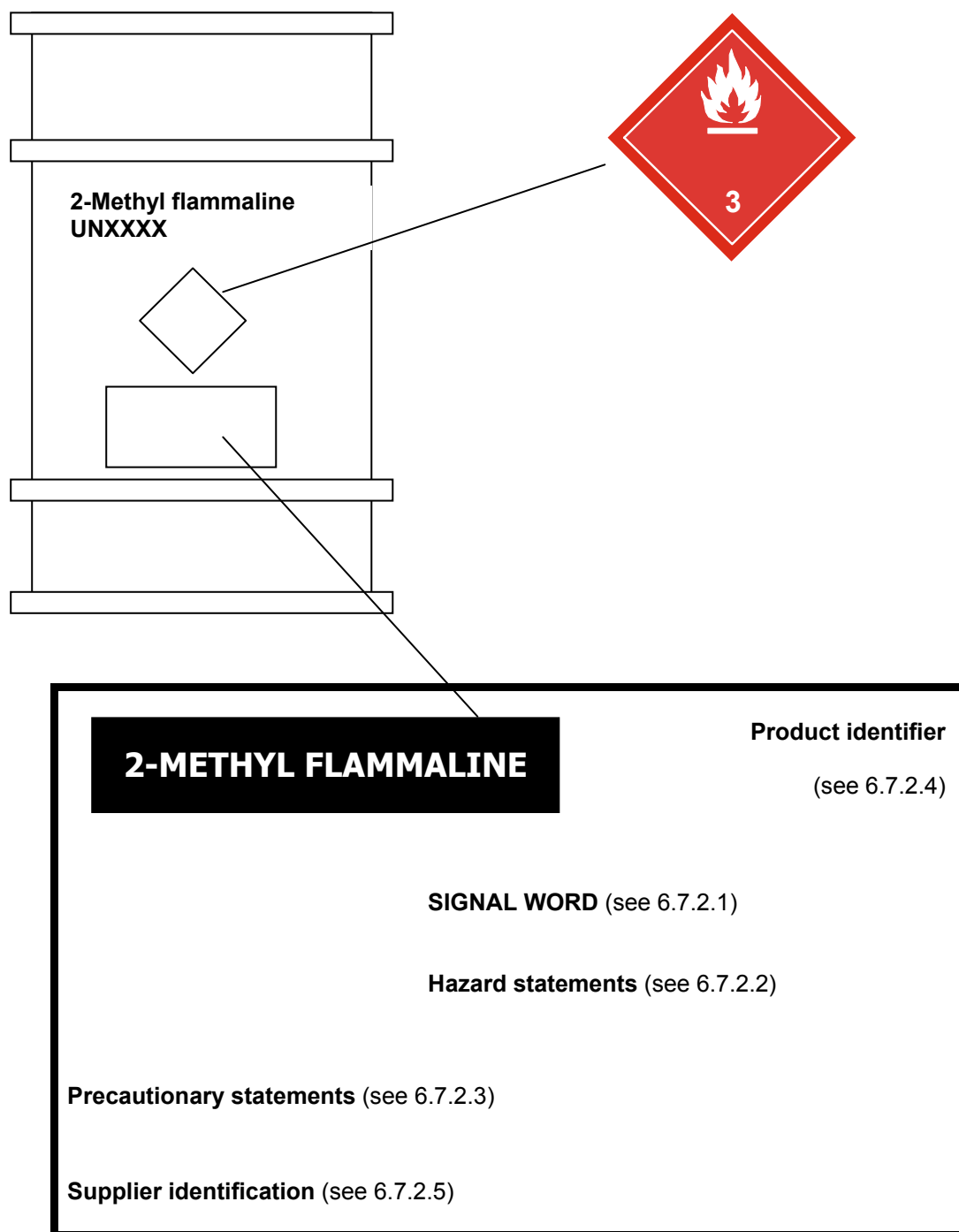


<b>BLAHZENE SOLUTION</b>		<b>Product identifier</b> (see 6.7.2.4)
	<b>SIGNAL WORD</b> (see 6.7.2.1)	
	<b>Hazard statements</b> (see 6.7.2.2)	
<b>Precautionary statements</b> (see 6.7.2.3)		
<b>Supplier identification</b> (see 6.7.2.5)		

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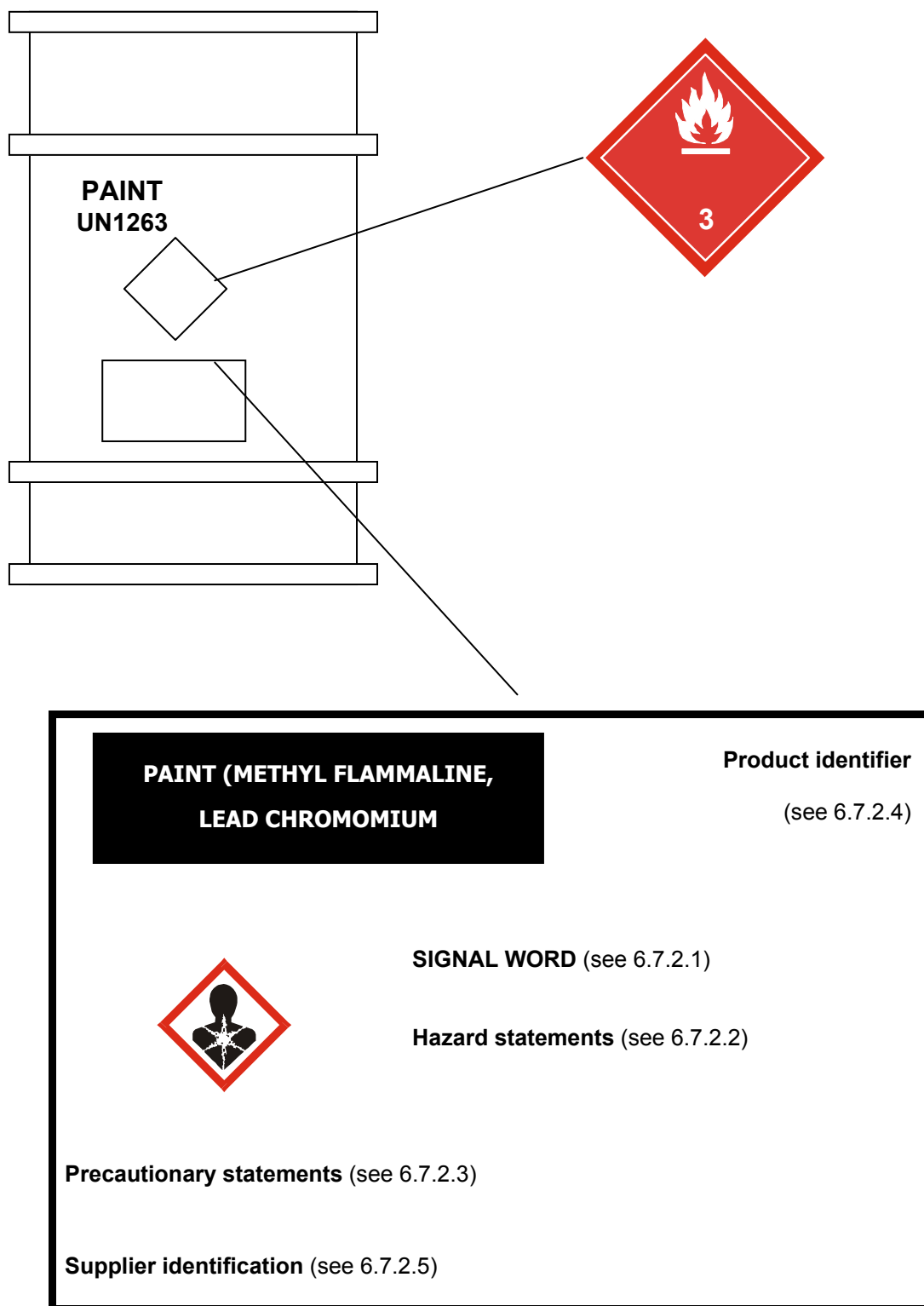
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### Example 4: Single packaging (210 L drum) for a category 2 flammable liquid



NOTE The GHS label and the transport mark, label and flammable liquid hazard pictogram in accordance with SANS 10229-1 or SANS 10233, as applicable, may also be presented in a combined format (see Example 7).

**Example 5: Single packaging for a substance that is a category 1 specific target organ toxicant and a category 2 flammable liquid**

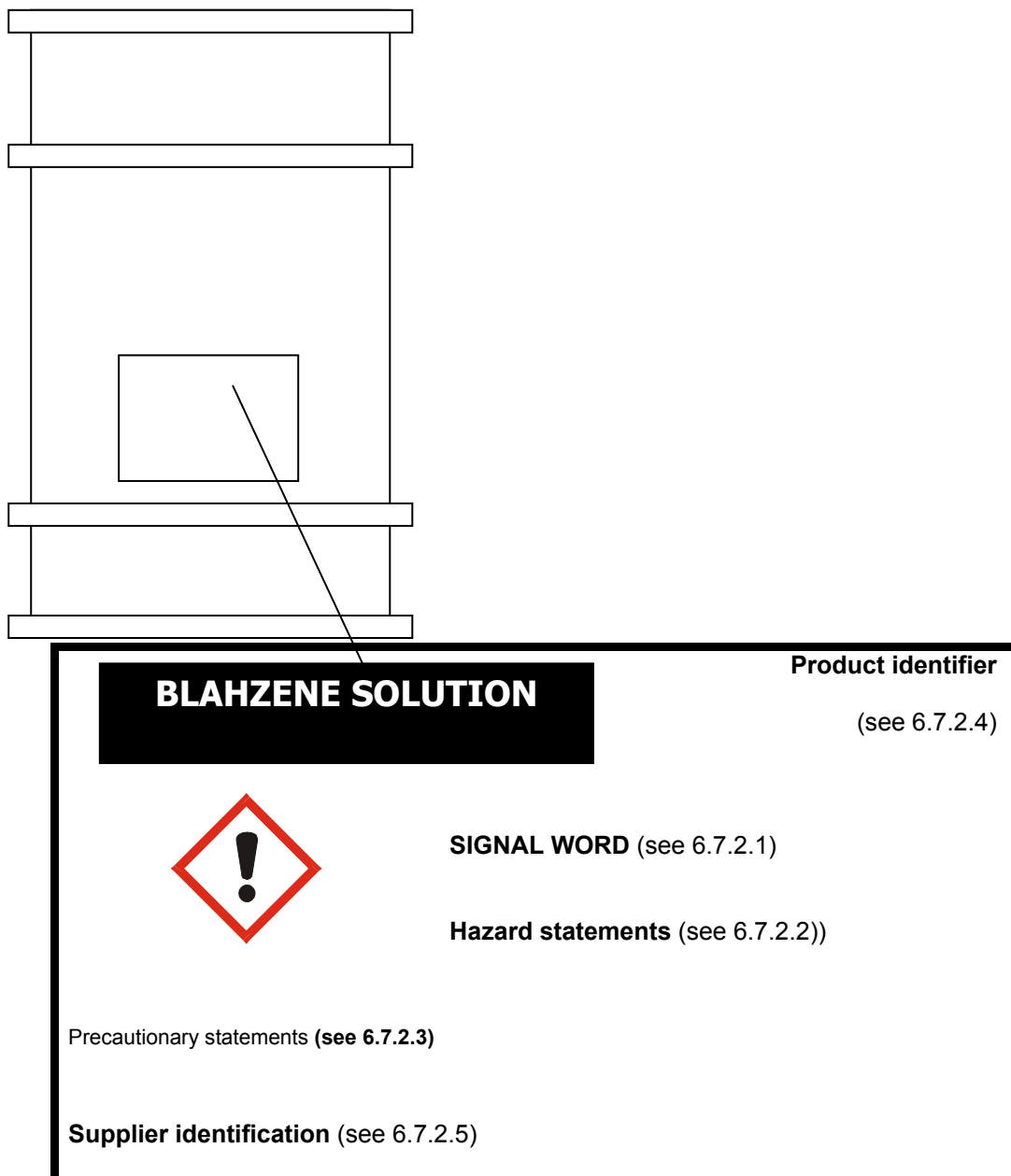


NOTE The GHS label and the transport mark, label and flammable liquid hazard pictogram in accordance with SANS 10229-1 or SANS 10233, as applicable, may also be presented in a combined format (see Example 7).

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### Example 6: Single packaging for substance that is a category 2 skin irritant and a category 2A eye irritant



### **Example 7: Single packaging using three adjacent panels to convey multiple hazards**

The following requirements apply when transport and GHS information appear on a single packaging:

- a) label elements shall be placed on the packaging in such a way that the needs of the different sectors are addressed;
- b) transport pictograms shall convey information immediately in an emergency situation. The pictograms shall be discernible from a distance, as well as in conditions that are smoky or that otherwise partially obscure the package;
- c) transport pictograms shall be distinct in appearance from pictograms intended solely for non-transport purposes that help to distinguish them;
- d) transport pictograms may be placed on a separate panel of a GHS label to distinguish them from the GHS information. Alternatively, the transport information may be placed adjacent to the GHS label on the packaging; and
- e) transport pictograms and GHS pictograms may be distinguished by adjusting their size. Generally speaking, the size of the GHS pictogram(s) should be proportional to the size of the text of the other label elements. This would generally be smaller than the transport pictograms, but such size adjustments should not affect the clarity or comprehensibility of the GHS pictograms.

## Example 7: Single packaging using three adjacent panels to convey multiple hazards *(continued)*

Product classified as (1) category 2 flammable liquid, (2) category 4 acute toxicity by inhalation, and (3) category 2 specific target organ/systematic toxicity, repeated exposure.

CODE

PRODUCT NAME

\*

COMPANY NAME

Street Address

City, State, Postal Code, Country

Phone Number

Emergency Phone Number

DIRECTIONS FOR USE:

XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXX

Fill weight: XXXX  
Gross weight: XXXX  
Expiration date: XXXX

Lot number: XXXX  
Fill date: XXXX



**Danger**  
Keep out of the reach of children.  
Read label before use.

Highly flammable liquid and vapour.  
Harmful if inhaled.  
May cause liver and kidney damage through  
prolonged or repeated exposure.

Keep container tightly closed.  
Keep away from heat/sparks/open flame – No  
smoking.  
Use only outdoors or in a well-ventilated area.  
Do not breathe fume/gas/mist/vapours/spray.  
Wear protective gloves and eye/face protection [as  
specified ...]

Ground/bond container and receiving equipment.

IN CASE OF FIRE use [as specified] for extinction [Universal Product Code (UPC)]

FIRST AID

IF INHALED: Remove to fresh air and keep at rest  
in a position comfortable for breathing.  
Call a Poison Center or doctor/physician if you feel  
unwell.

Store in a cool, well-ventilated place.

UN Number  
Proper shipping  
name

### **Example 8: Combination packaging and single packaging for pesticides using three adjacent panels**

#### **Combination packaging when a pesticide is not hazardous for transport**

The following requirements apply to the labels of a combination packaging when a pesticide is not hazardous for transport but hazardous for other sectors:

- a) **outer packaging:** – no transport mark and label, and no hazard diamond. The GHS label shall be provided.
- b) **inner packaging:** – receptacles provided with the GHS warning label and supplemental information (see 6.7.2.9.2 and 6.7.5.12).

#### **Combination packaging when a pesticide is hazardous for transport**

The following requirements apply to labels of a combination packaging when a pesticide is hazardous for transport:

- a) **outer packaging:** – transport marks and relevant hazard class diamond in accordance with SANS 10229-1 or SANS 10233, as applicable (see also Example 2).
- b) **inner packaging** – receptacles with the GHS warning label and supplemental information required (see 6.7.2.9.2 and 6.7.5.12).

#### **Single packaging when a pesticide is not hazardous for transport**

Where a pesticide is not hazardous for transport, a single packaging shall be provided with the GHS warning label and the supplemental information required (see 6.7.2.9.2 and 6.7.5.12).

#### **Single packaging when a pesticide is hazardous for transport**

Where a pesticide is hazardous for transport, a single packaging shall be provided with the transport mark and the relevant hazard class diamond in accordance with SANS 10229-1 or SANS 10233, as applicable, as well as the required GHS information (see 6.7.2.9.2, 6.7.5.12 and Example 7).









#### **Additional hazard communication requirements**

The following additional communication requirements apply:

- a) the package shall be accompanied by safety advice and directions for use in the form of an insert if it is physically impossible to include the advice on the label of the package; and
- b) the label can be designed with two or more adjacent panels to convey the label information if the label is of adequate size.

## Example 8: Combination packaging and single packaging for pesticides using three adjacent panels *(continued)*

Pesticide classified as hazard category 2 for acute oral toxicity and hazard category 1 for acute aquatic toxicity

<b>INSECTTOX EC</b>	
<p>Registration No.</p> <p style="text-align: center;"><b>DANGER</b> Read label before use</p> <p><b>HAZARDS</b></p> <p>Toxic if swallowed May be harmful in contact with skin Causes serious eye irritation Very toxic to aquatic life</p> <p>Active ingredient(s)</p> <p style="text-align: center;"><b>COMPANY NAME</b> (Registration holder)</p> <p>Full street address Phone number Emergency phone number</p> <p>Batch number Date of manufacture Net volume</p>	<p><b>PRECAUTIONS</b></p> <p>Do not eat, drink or smoke when using this product Wear protective gloves Wash hands thoroughly with soap and water after handling Store locked up and out of reach of children Store in a cool well-ventilated place Avoid release to the environment Triple rinse empty container, and puncture the container so that it cannot be re-used.</p> <p><b>SYMPTOMS OF HUMAN POISONING</b></p> <p>Burning, itching or tingling sensations of the skin that readily disappear after 24 h. Inhalation causes nasal discharge, scratchy throat, convulsions and tremors. Systemic symptoms include dizziness, headache, nausea and vomiting.</p> <p><b>FIRST AID</b></p> <p>IF SWALLOWED: Immediately call a doctor and show the label.</p> <p>IF ON SKIN: Immediately remove all contaminated clothing and rinse skin with plenty of water.</p> <p>IF IN EYES: Rinse with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.</p> <p><b>Note to physician</b></p> <p>Antidote is not available. Treat symptomatically and supportively. In case of ingestion, consider gastric lavage with water or 5% sodium bicarbonate solution. Convulsions should be treated with anti-convulsants. Vomiting may be induced by using Ipecac syrup.</p>
 	
     	



# **ANNEX F**

**(informative)**

## **AN EXAMPLE OF CLASSIFICATION IN THE GLOBALLY HARMONIZED SYSTEM**

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**Annex F**  
(informative)

**An example of classification in the Globally Harmonized System**

**F.1 Classification proposal**

**F.1.1** The following classification proposal draws on the GHS criteria and includes brief statements about the proposal for each health hazard class and details of all the available scientific evidence.

**F.1.2** Classification is proposed for both the acute toxicity and the corrosiveness of this substance based on standard and non-standard animal studies.

<b>Proposed classification</b>	GHS: Acute oral toxicity of hazard category 4 Acute dermal (skin) toxicity of hazard category 3 Skin irritation/corrosion of hazard category 1C Eye irritation/serious eye damage of hazard category 1 Flammable liquid of hazard category 4
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**F.2 Identification of the substance**

<b>1.1 EINECS name or IUPAC name</b>	Globalene Hazexyl Systemol
	CAS No. 999-99-9 EINECS No. 222-222-2
<b>1.2 Synonyms (state ISO name if available)</b>	2-Hazanol Globalethylene
<b>1.3 Molecular formula</b>	C <sub>x</sub> H <sub>y</sub> O <sub>z</sub>
<b>1.4 Structural formula</b>	
<b>1.5 Purity, by mass</b>	
<b>1.6 Significant impurities or additives</b>	
<b>1.7 Known uses</b>	<i>Industrial:</i> Solvent for surface coatings and cleaning solutions. Chemical intermediate for globalexyl noxy iloate.  <i>General public:</i> Toilet cleaner

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### F.3 Physico-chemical characteristics

Classification as a flammable liquid of hazard category 4 is proposed for the physico-chemical endpoints.

<b>2.1 Physical form</b>	Liquid
<b>2.2 Molecular mass</b>	146,2
<b>2.3 Melting point/range, °C</b>	-45
<b>2.4 Initial boiling point/ boiling range, °C</b>	208,3
<b>2.5 Decomposition temperature, °C</b>	
<b>2.6 Vapour pressure, mm Hg at ...°C</b>	7
<b>2.7 Relative density</b>	0,887 – 0,890
<b>2.8 Vapour density (air = 1)</b>	5,04
<b>2.9 Fat solubility, mg/kg at ... °C</b>	
<b>2.10 Water solubility, %, by mass, at °C</b>	Slightly soluble (0,99)
<b>2.11 Partition coefficient, log Pow</b>	
<b>2.12 Flammability:</b> – flash point, °C – explosive limits, %, by volume – auto-ignition temp, °C	<b>closed cup:</b> 81,7 <b>lower limit:</b> 1,2 <b>open cup:</b> 90,6 <b>upper limit:</b> 8,4
<b>2.13 Explosivity</b>	No data available
<b>2.14 Oxidizing properties</b>	
<b>2.15 Other physico-chemical properties</b>	

## F.4 Health characteristics

### F.4.1 Acute toxicity

#### F.4.1.1 Oral

Classification under GHS hazard category 4 (300-2000 mg/kg) is justified.

Species	<i>LD</i> <sub>50</sub> mg/kg	Observations and remarks	Reference (see F.13)
Rat	1480	No further details were available.	
Rat	1500 (males) 740 (females)	The <i>LD</i> <sub>50</sub> values in mg/kg were calculated from mL/kg by using the relative density of 0.89.	

#### F.4.1.2 Inhalation

No deaths or signs of overt toxicity occurred in test animals exposed to the saturated vapour concentration of approximately 0,5 mg/L. Therefore, the available data do not support classification.

Species	<i>LC</i> <sub>50</sub> mg/L	Exposure time h	Observations and remarks	Reference (see F.13)
Rat	> 83 ppm (approx equal to 0,5 mg/L)	4	No deaths, clinical signs or gross lesions occurred at 83 ppm (85 ppm is stated to be the saturated vapour concentration at room temperature).	
Rat	Not stated	6	The test animals were exposed to the saturated vapour concentration at room temperature (assumed to be 85 ppm). No deaths occurred and no signs of gross pathology were observed.	
Rat	Not stated	8	No deaths occurred with exposure to the "saturated vapour concentration" at room temperature (assumed to be 85 ppm).	

#### F.4.1.3 Skin (dermal)

Classification under GHS hazard category 3 (200-1000 mg/kg) is justified.

Species	<i>LD</i> <sub>50</sub> mg/kg	Observations and remarks	Reference (see F.13)
Rat	790	No further details were available.	
Rabbit (5/sex/ group)	720 (males) 830 (females)	The test animals were exposed to the substance at a concentration of up to 3560 mg/kg for 24 h. All but 2 of the animals that died did so during the application period. Following the exposure period, local dermal toxicity (erythema, oedema, necrosis and ecchymoses) was reported (number of test animals not stated), and persisted throughout the 14 d post-application observation period. Ulceration was also noted (number of test animals not stated) at the end of the observation period.	

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### F.5 Skin irritation/corrosion

**F.5.1** There are conflicting reports concerning the irritant nature of this substance. In a dedicated skin irritation study reported in the same paper as the acute dermal study, the author states that “necrosis” was observed in 3 of 6 treated rabbits which was still present on the last day of observation (day 7), along with mild to moderate erythema. Mild to marked oedema was also observed during the course of the study but had resolved within the 7-day observation period. Given that one animal showed no evidence of any skin response in this study and that only slight to moderate skin irritation was observed in the other animals, the observation of “necrosis” in three of the animals is somewhat surprising. An acute dermal (skin) toxicity study in rabbits also reported signs of skin irritation including the description ‘necrosis’ and ulceration but did not quantify the number of animals affected. In contrast to these findings, an old and briefly reported study indicated that there was little or no indication of skin irritation in rabbits.

**F.5.2** Similarly, mixed skin irritation findings were observed with a closely related substance for which no necrosis and skin irritation had been reported. In addition, a secondary source indicates that some other similar substances cause “moderate” skin irritation, and that prolonged exposure to this group of substances may cause burns. However, similar substances with a much shorter chain length are not considered to be skin irritants.

**F.5.3** Reported necrosis in both the acute dermal and skin irritation studies cannot be dismissed and, taken together with the findings seen with structurally similar substances, this justifies classification. There are 3 hazard categories under the GHS for classification as corrosive. The data do not match the criteria readily, but hazard category 1C would be appropriate since the necrotic lesions observed occurred after an exposure period of 4 h. There is no evidence to suggest that significantly shorter exposures would produce skin corrosion.

Species	Number of animals	Exposure time h	Conc. %, by mass	Dressing: (occlusive, semi-occlusive, open)	Observations and remarks (specify degree and nature of irritation and reversibility)	Reference (see F.13)
Rabbit	6	4	0,5	Occlusive	No signs of irritation were observed in one animal, and only slight erythema (grade 1) in another on day 1, which had resolved by day 7. Four animals showed a mild to moderate erythema (grade 1-2) and a mild to marked oedema (grade 1-3) after removal of the dressing. The oedema had resolved by day 7 post-exposure. “Necrosis” at the application site was reported in 3/6 rabbits from day 1 until the end of the observation period on day 7. Desquamation was observed in 4/6 rabbits on day 7.	
Rabbit (albino)	5	24	Conc. not stated	Not stated	Little or no signs of skin irritation were found in this poorly reported study.	

## **F.6 Serious damage to eyes/eye irritation**

The only available study exposed rabbits to considerably lower amounts of the test substance than that recommended by the standard protocols for this endpoint. Relatively severe (for example, conjunctival redness grade 3) but reversible effects were observed. It is predictable that under standard test conditions, the effects on the eye would be very severe and consequently GHS hazard category 1 (irreversible effects on the eye) would be justified.

<b>Species</b>	<b>Number of animals</b>	<b>Concentration %, by mass</b>	<b>Observations and remarks (specify degree and nature if irritation, any serious lesions, reversibility)</b>	<b>Reference (see F.13)</b>
Rabbit	6	0,005	One hour post-instillation conjunctival redness (grade 3) and discharge (grade 2.8) observed. The mean scores for the 24 h, 48 h and 72 h readings for corneal opacity, iris, conjunctival redness, chemosis and discharge were all approx 0,5. All lesions had resolved by day 7.	
Rabbit	60	1 and 5	A report in the secondary literature of severe eye injury observed in rabbits associated with instillation of an amount of 5 % that has not been stated, could not be substantial as the information was not found in the reference stated.	

## **F.7 Skin sensitisation and respiratory sensitisation**

No data are available. There are no additional grounds for concern (for example, structure activity relationships) and therefore no classification is proposed.

## **F.8 Specific target organ toxicity following single or repeated exposure**

### **F.8.1 Toxicity following a single exposure**

No reliable information is available about the potential of this substance to produce specific, non-lethal target organ toxicity arising from a single exposure. Therefore, under GHS, no classification for target organ toxicity – single exposure, is proposed.

### **F.8.2 Toxicity following repeated exposure**

#### **F.8.2.1 Oral**

No oral repeat dose animal studies or human evidence are available and therefore no classification is proposed.

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### F.8.2.2 Inhalation

There was no evidence of adverse toxicity in a 13-week rat inhalation study at 0,43 mg/L (approx. 72 ppm), an exposure level close to the saturated vapour concentration. In accordance with the GHS criteria, a classification is not justified.

Species	Conc. mg/L	Exposure time h	Duration of treatment	Observations and remarks (specify group size, NOEL and effects of major toxicological significance)	Reference (see F.13)
Rat (F344)  20/sex/group (plus 10/ sex/group – 4 week recovery groups)	0,12; 0,24 and 0,425	6	5 d/week for 13 weeks	No deaths occurred. Decreased weight gain was observed in high dose animals of both sexes and medium dose females. No toxicologically significant changes in haematological or urinalysis parameters were observed. High dose females showed an increase in alkaline phosphatase. High and medium dose males showed a statistically significant increase in absolute and relative kidney weight. A small increase in absolute liver weight (12 %) was observed in high dose females. However, there were no gross or histopathological changes in any organs examined.	

### F.8.2.3 Dermal

Dermal exposure of test rabbits to 444 mg/kg of test substance over a period of 11 d resulted in haematological changes that were not quantified. Therefore, due to the limited information provided, no conclusions can be drawn from this study and no classification is proposed.

Species	Dose mg/kg	Exposure time h	Duration of treatment	Observations and remarks (specify group size, NOEL and effects of major toxicological significance)	Reference (see F.13)
Rabbit	nil; 44; 222 and 444	6	9 doses applied over 11 d	This is an unpublished study reported in the secondary literature. Decreases in haematological parameters (not quantified), were noted in top dose animals. No description of local effects was provided.	

## F.9 Carcinogenicity (including chronic toxicity studies)

No data available – no classification proposed.



## **F.10 Mutation in germ cells**

### **F.10.1 General**

Secondary literature reported negative results *in vitro* from Ames, cytogenetics, and gene mutation tests. No *in vivo* data are available. These data do not support classification.

### **F.10.2 *In vitro* studies**

<b>Test</b>	<b>Cell type</b>	<b>Concentration range</b>	<b>Observations and remarks</b>	<b>Reference (see F.13)</b>
Ames	Salmonella (strains not stated)	0,3 – 15 mg/plate	Negative in the presence, and absence, of metabolic activation. Reported in an unpublished study from a secondary source. No further information is available.	
IVC	CHO	0,1 – 0,8 mg/mL (-S9), 0,08 – 0,4 mg/mL (+S9)	Negative in the presence, and absence, of metabolic activation. Reported in an unpublished study from a secondary source. No further information is available.	
Gene mutation	CHO	Not stated	Negative. Reported in an unpublished study from a secondary source. No further information is available.	
SCE	CHO	Not stated	Negative. Reported in an unpublished study from a secondary source. No further information is available.	

## **F.11 Reproductive toxicity-fertility**

No data available – no classification proposed.

## **F.12 Reproductive toxicity**

No evidence of developmental toxicity in rats or rabbits following inhalation exposure to levels inducing slight maternal toxicity. It is noted that although shorter chain related substances are classified for developmental toxicity, this toxicity decreases with increasing chain length such that there is no evidence of this hazard. No classification is proposed.

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Species	Route	Dose	Exposure time	Observations and remarks	Reference (see F.13)
Rat	Inhalation	21 ppm (0,12 mg/L), 41 ppm (0,24 mg/L) and 80 ppm (0,48 mg/L)	6-15 d of gestation	The substance was tested up to approximately the saturated vapour concentration.  Decreases in dam body weight gain, associated with decreases in food consumption, were observed in the medium and high dose groups during the exposure period. There was no evidence of developmental toxicity.	
Rabbit	Inhalation	21 ppm (0,12 mg/L), 41 ppm (0,24 mg/L) and 80 ppm (0,48 mg/L)	6-18 d of gestation	The substance was tested up to approximately the saturated vapour concentration.  Decrease in absolute body weight during the exposure period was observed in the high dose animals. There was no evidence of developmental toxicity.	

### F.13 References

Give the full reference of the publications from which the data were obtained. Provide each reference with a number and indicate this number against the relevant data.

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# **ANNEX G**

## **GUIDANCE ON HAZARDS TO THE AQUATIC ENVIRONMENT**

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## **Annex G**

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### **Guidance on hazards to the aquatic environment**

#### **G.1 Introduction**

**G.1.1** In developing the set of criteria for identifying substances hazardous to the aquatic environment, it was agreed that the detail needed to properly define the hazards to the environment resulted in a complex system for which some suitable guidance would be necessary. Therefore, the purpose of this annex is twofold:

- a) to provide a description of, and guidance to, how the system works; and
- b) to provide a guidance to the interpretation of data for use in applying the classification criteria.

**G.1.2** The hazard classification scheme has been developed with the object of identifying those chemical substances that present, through the intrinsic properties they possess, a danger to the aquatic environment. In this context, the aquatic environment is taken as the aquatic ecosystem in freshwater and marine, and the organisms that live in it. For most substances, the majority of data available addresses this environmental compartment. The definition is limited in scope in that it does not, as yet, include aquatic sediments, nor higher organisms at the top end of the aquatic food-chain, although these may to some extent be covered by the criteria selected.

**G.1.3** Although limited in scope, it is widely accepted that this compartment is vulnerable in that it is the final receiving environment for many harmful substances, and the organisms that live there are sensitive. It is also complex since any system used to identify hazards to the environment should define those effects in terms of wider effects on ecosystems rather than on individuals within a species or population. A limited set of specific properties of chemical substances have been selected through which the hazards can be best described:

- a) aquatic toxicity;
- b) lack of degradability; and
- c) potential or actual bioaccumulation.

The rationale for the selection of these data as the means to define the aquatic hazard will be described in more detail in G.2.

**G.1.4** The application of the criteria is also limited, at this stage, to chemical substances (see 3.1.81). The term “substances” covers a wide range of chemicals, many of which pose difficult challenges to a classification system based on rigid criteria. This annex provides some guidance as to how these challenges can be dealt with based on experience in use and clear scientific rationale. While the harmonized criteria apply most easily to the classification of an individual substance, some materials that fall under this category are frequently referred to as “complex mixtures”. In most cases they can be characterized as a homologous series of substances with a certain range of carbon chain length/number, or degree of substitution. Special methodologies have been developed for testing that provide data for evaluating the intrinsic hazards to aquatic organisms, bioaccumulation and degradation. For the purpose of this annex, these materials will be referred to as “complex substances” or “multi-component substances”.

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**G.1.5** Each of these properties (that is, aquatic toxicity, degradability and bioaccumulation) could present a complex interpretational problem, even for experts. While internationally agreed testing guidelines exist and should be used for any, and all new, data produced, many data usable in classification will not have been generated according to such standard tests. Even where standard tests have been used, some substances, such as complex substances, hydrolytically unstable substances and polymers present difficult interpretational problems when the results have to be used within the classification scheme. Thus data are available for a wide variety of both standard and non-standard test organisms, both marine and freshwater, of varying duration and by utilising a variety of endpoints. Degradation data can be biotic or abiotic and can vary in environmental relevance. The potential to bio-accumulate can, for many organic chemicals, be indicated by the octanol-water partition coefficient. It can however, be affected by many other factors and these also need to be taken into account.

**G.1.6** The objective of the Globally Harmonized System is that, having agreed on a common set of criteria, a common data-set should be used so that once classified, the classification is globally accepted. For this to occur, there should first be a common understanding of the type of data that can be used in applying the criteria, both in type and quality and subsequently, a common interpretation of the data when measured against the criteria. The guidance encompassed in this annex was developed to expand and explain the criteria in such a way that a common understanding of their rationale and a common approach to data interpretation may be achieved. This is of particular importance since the harmonized system applied to the “universe of chemicals” relies heavily on self-classification by manufacturers and suppliers. Classifications should therefore be accepted across national boundaries without the necessity of receiving regulatory scrutiny. This annex seeks to inform the reader on a number of key areas that would lead to classification in a consistent manner, thus ensuring a truly harmonized and self-operating system.

**G.1.7** Firstly, the annex provides a detailed description of the criteria, a rationale for the criteria selected, and an overview of how the scheme works in practice (see G.2). It addresses common data sources, the need to apply quality criteria, how to classify when the data are incomplete or when a large amount of data leads to an ambiguous classification, and other commonly encountered classification problems.

**G.1.8** Secondly, the annex provides detailed expert advice on the interpretation of data derived from available databases, including the use non-standard data, and specific quality criteria that might apply for individual properties. The problems of data interpretation for “difficult substances”, those substances for which standard testing methods either do not apply or give difficult interpretational problems, are described and advice provided on suitable solutions. The emphasis is on data interpretation rather than testing since the system, as far as possible, relies on the best available existing data and data required for regulatory purposes. The three core properties, aquatic toxicity (G.3), degradation (G.4) and bioaccumulation (G.5) are treated separately.

**G.1.9** The range of interpretational problems can be extensive with the result that interpretation always relies on the ability and expertise of the individuals responsible for classification. However, it is possible to identify some commonly occurring difficulties and provide guidance that distils accepted expert judgement that can act as an aid to achieving reliable and consistent results. Such difficulties can fall into a number of overlapping issues such as

- a) the application of the current test procedures to a number of types of substance,
- b) the interpretation of data derived both from these “difficult to test” substances and from other substances, and
- c) the interpretation of diverse data derived from a wide variety of sources.

**G.1.10** For many substances, the testing and interpretation of data present no problems when applying both the relevant OECD Guidelines and the classification criteria. Typical interpretational problems are characterized by the type of substance being studied and are commonly referred to as “difficult substances”:

- a) **Poor water soluble substances** – these substances are difficult to test because they present problems in solution preparation, in concentration maintenance and verification during aquatic toxicity testing. In addition, often available data for such substances were produced by using “solutions” in excess of the water solubility, resulting in major interpretational problems in defining the true  $L(E)C_{50}$  for the purposes of classification. Interpretation of the partitioning behaviour could also be problematic where the poor water solubility and octanol-water partition coefficient (see 3.1.59) are compounded by insufficient sensitivity in the analytical method. Water solubility could be difficult to determine and is frequently recorded as being less than the detection limit. This creates problems in interpreting both aquatic toxicity and bioaccumulation studies. In biodegradation studies, poor water solubility might result in low bioavailability and thus lower than expected biodegradation rates. The specific test method or the choice of procedures used can thus be of key importance.
- b) **Unstable substances** – substances that degrade (or react) rapidly in the test system present both testing and interpretational problems. It is necessary to determine whether the correct methodology has been used, whether the substance or the degradation/reaction product that has been tested, and whether the data produced are relevant to the classification of the parent substance.
- c) **Volatile substances** – these substances present problems when tested in open systems and measures should be taken to ensure adequate maintenance of exposure concentrations. Loss of test material during biodegradation testing is inevitable in certain methods and this leads to misinterpretation of the results.
- d) **Complex or multi-component substances** – substances (for example, hydrocarbon mixtures) that do not readily dissolve into a homogeneous solution, or multiple components that make monitoring impossible. Therefore, data derived from the testing of water-accommodated fractions (WAFs) for aquatic toxicity need to be considered for utilization in the classification scheme. Biodegradation, bioaccumulation, partition-coefficient behaviour and water solubility all present problems of interpretation as each component of the mixture might behave differently.
- e) **Polymers** – such substances often have a wide range of molecular mass, with only a fraction being water soluble. Special methods are available to determine the water-soluble fraction and these data need to be used in interpreting the test data against the classification criteria.
- f) **Inorganic compounds and metals** – these substances could react with other substances in the aquatic environment to produce a range of aquatic toxicities depending on such factors as pH, water hardness etc. Interpretational problems could arise from the testing of essential elements that are beneficial at certain levels. For metals and inorganic metal compounds, the concept of degradability has limited or no meaning. Likewise, data on bioaccumulation should be treated with care.
- g) **Surface active substances** – such substances could form emulsions resulting in difficulties to ascertain bioavailability, even with careful solution preparation. Micelle formation leads to an overestimation of the bio-available fraction even when “solutions” are apparently formed. This presents significant interpretation problems on water solubility, partition coefficient, bioaccumulation and aquatic toxicity studies.
- h) **Ionizable substances** – the extent of ionization of these substances depend on the level of counter ions in the aquatic environment. For example, acids and bases show radically different partitioning behaviour depending on the pH.

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- i) **Coloured substances** – problems occur with algal/aquatic plant testing because of the blocking of incident light.
- j) **Impurities** – the amount and chemical nature of impurities in the same substance could differ between production batches. Interpretation problems could arise where either, or both, the toxicity and water solubility of the impurities are greater than the parent substance, thus potentially influencing the toxicity data in a significant way.

**G.1.11** A wide range of degradation data is available in literature and needs to be interpreted according to the criteria for rapid degradability. Guidance on how to use degradation data obtained by non-standard test methods is given in G.4, including the use of half-lives where available, of primary degradation, of soil degradation rates and their suitability for extrapolation to aquatic degradation and of environmental degradation rates.

**G.1.12** Methods to determine the bioaccumulation potential are given in G.5. The clause also covers the relationship between the partition coefficient criteria and the bio-concentration factor (BCF), provides guidance on the interpretation of existing data, estimation of the partition coefficient by means of QSARs (see 11.2.7, G.3.3.5, G.5.2.4.3 and G.5.5.3) when no experimental data are available and deals with specific problems identified in G.1.9 for “difficult” substances.

**G.1.13** Clause G.6 covers general issues concerning the use of QSARs within the classification system. As a general approach, experimental data should be used rather than QSAR data when such data are available. The use of QSARs should thus be limited to cases when no reliable data are available. It should also be noted that not all substances are suitable for the application of QSAR estimations.

**G.1.14** Problems associated with the classification of metals and their compounds as hazardous to the aquatic environment are covered in G.6. Criteria such as biodegradability and octanol-water partition coefficient cannot be applied for the classification of metals and metal compounds, although the principle of lack of destruction via degradation and bioaccumulation remain important concepts. Thus it is necessary to adopt a different approach. Metals and metal compounds could undergo interactions with the aquatic environment that affect the solubility of the metal ion, partitioning from water and the species of metal ion that exist in water. Generally, the dissolved metal ions are of concern for toxicity. The interaction of the substance with the aquatic environment might either increase or decrease the level of ions and hence toxicity. It is thus necessary to consider whether metal ions are likely to be formed from the substance and dissolve in the water, and if so, whether they are formed rapidly enough to cause concern.

## **G.2 The harmonized classification scheme**

### **G.2.1 Classification categories and criteria**

The hazard categories for acute and chronic aquatic toxicity and their related criteria are given in clause 11.

### **G.2.2 Rationale**

**G.2.2.1** The harmonized system for classification recognizes that the intrinsic hazard to aquatic organisms is represented by both the acute and chronic (longer-term) toxicity of a substance. Distinction could be made between the acute hazard and the chronic hazard and therefore the hazard categories are defined for both properties representing a gradation in the level of hazard identified. Thus, the hazard identified by chronic category 1 is more severe than chronic category 2.



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Since the acute hazard and chronic hazard represent distinct types of hazard, they are not comparable in terms of their relative severity and should be applied independently for the classification of substances.

**G.2.2.2** The principal hazard classes defined by the criteria relate largely to the potential for chronic hazard. This reflects the overriding concern with respect to chemicals in the environment, namely that the effects caused are usually sub-lethal, for example effects on reproduction, and caused by longer-term exposure. Although chronic hazards are the main concern, it should be recognized that, for packaged goods, environmental release would be limited in scope. Furthermore, chronic toxicity data are expensive to generate and generally not readily available for most substances. On the other hand, acute toxicity data are frequently readily available, or can be generated to highly standardized protocols. Acute toxicity has therefore been used as the core property in defining both the acute and the chronic hazard. Nevertheless, it has been recognized that, where chronic toxicity data are available, it should be used in defining the appropriate hazard category. The development of specific criteria using such data is thus a high priority in the future development of the scheme.

**G.2.2.3** While acute toxicity is not a sufficiently accurate predictor of chronic toxicity to be used solely and directly for establishing a hazard, it is considered that, in combination with either a potential for bioaccumulation (that is, a  $\log K_{ow} \geq 4$  unless  $BCF < 500$ ) or a potential longer-term exposure (that is, lack of rapid degradation), it could be used as a suitable surrogate for classification purposes. Substances exhibiting acute toxicity and bioaccumulation, normally show chronic toxicity at a significantly lower concentration. Precise ratios of acute toxicity to chronic toxicity are difficult to predict and thus the surrogate data are generally precautionary. Equally, substances that do not rapidly degrade have a higher potential for giving rise to longer-term exposures that might result in long-term toxicity being realised. For example, chronic category 1 should be assigned if the following criteria are met:

- a)  $L(E)C_{50}$  for any appropriate aquatic species  $\leq 1$  mg/L and a potential for bioaccumulation ( $\log K_{ow} \geq 4$  unless  $BCF < 500$ ) (see G.3 and G.5); or
- b)  $L(E)C_{50}$  for any appropriate aquatic species  $\leq 1$  mg/L and a lack of rapid degradation (see G.3 and G.4).

**G.2.2.4** Acute toxicity is not reported in toxicity tests performed at the solubility limit for poorly water soluble substances, normally considered as those having a water solubility of  $< 1$  mg/L. However, if the  $BCF \geq 500$ , or if absent, the  $\log K_{ow} \geq 4$  (indicating a bioaccumulation potential) and the substance are also not rapidly degradable, chronic category 4 is assigned as a “safety net” classification. The exposure duration in short term tests might be too short for a steady state concentration of the substance to be reached in the test organisms. Thus, even though no acute toxicity has been detected in a short-term (acute) test, it remains a possibility that such non-rapidly degradable and bioaccumulative substances could exert chronic effects, particularly since such low degradability leads to an extended exposure **period** in the aquatic environment.

**G.2.2.5** It is not possible to test all species present in an aquatic ecosystem for acute aquatic toxicity. Representative species are therefore chosen which cover a range of trophic (concerned with nutrition) levels and taxonomic (living and extinct organisms) groupings. The taxonomic group chosen, that is, fish, crustacea and aquatic plants that represent the “base-set” in most hazard profiles, represent a minimum data-set for a fully valid description of hazard. The lowest of the available toxicity values are normally used to define the hazard category. Given the wide range of species in the environment, the three species tested are a poor surrogate and therefore the lowest value should be used for reasons of caution to define the hazard category. In doing so, it is recognized that the distribution of species sensitivity could be several orders of magnitude wide and that more, or less, sensitive species (or both) are present in the environment. Thus, when data are limited, the use of the most sensitive species tested gives a cautious but acceptable definition of the hazard. In some cases it might not be appropriate to use the lowest toxicity value as the basis for

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classification, for example where the sensitivity distribution could be defined with more accuracy than would normally be possible, such as when large data-sets are available. However, large data sets should be evaluated with due caution.

### **G.2.3 Application**

**G.2.3.1** In deciding whether a substance should be classified, a search of appropriate databases and other sources of data should be made for the following elements:

- a) water solubility;
- b) octanol/water partition coefficient ( $\log K_{ow}$ );
- c) fish bioconcentration factor (BCF);
- d) acute aquatic toxicity ( $L(E)C_{50}$ );
- e) chronic aquatic toxicity (NOECs);
- f) degradation (and specifically evidence of ready biodegradability); and
- g) water stability.

The water solubility and water stability data, although not used directly in the criteria, nevertheless facilitate in the data interpretation of the other properties (see G.1.9).

**G.2.3.2** The relevant available aquatic toxicity data should be reviewed before commencing with a classification. It is necessary to consider all the available data and select those that meet the necessary quality criteria for classification. If the available data do not meet the quality criteria required by the internationally standardized methods, it would be necessary to examine any available data to determine whether a classification could be made. If the data indicate that the acute aquatic toxicity  $L(E)C_{50} > 100$  mg/L for soluble substances, then the substance is not classified as hazardous. There are a number of cases where no effects are observed in the test and the aquatic toxicity is thus recorded as greater than the water solubility value, that is, there is no acute toxicity within the range of the water solubility in the test media. Where this is the case, and the water solubility in the test media is  $\geq 1$  mg/L, again, no classification applies.

**G.2.3.3** When the aquatic toxicity data are below 100 mg/L, it is necessary to first decide which hazard category is applicable and then determine whether the chronic or the acute subclass (or both), should be applied. This can be achieved by examining the available data on the partition coefficient ( $\log K_{ow}$ ) and the available data on degradation. If either the  $\log K_{ow} \geq 4$  or the substance cannot be considered as rapidly degradable, the appropriate chronic hazard category and the corresponding acute category are applied independently. It should be noted that, although the partition coefficient is the most readily available indication of a potential to bioaccumulate, an experimentally derived BCF is preferred. A  $BCF \geq 500$  indicates that bioaccumulation is sufficient for classification in the appropriate chronic hazard category. If the substance is both rapidly degradable and has a low potential to bioaccumulate ( $BCF < 500$  or, if absent,  $\log K_{ow} < 4$ ), then chronic toxicity does not apply and only the acute hazard categories need be applied (see G.2.1 and clause 11).

**G.2.3.4** Substances with a water solubility in the test media of  $< 1$  mg/L, and for which no aquatic toxicity has been found, should be further examined to determine whether chronic category 4 is applicable. Thus, if the substance is not rapidly degradable and has a potential to bioaccumulate ( $BCF \geq 500$  or, if absent,  $\log K_{ow} \geq 4$ ), chronic category 4 should be applied.

## **G.2.4 Data availability**

The data used for the classification of a substance could be derived from data required for regulatory purposes as well as the relevant literature. Furthermore, a number of internationally recognized databases exist which can act as a good starting point for classification. Such databases vary widely in quality and comprehensiveness and it is unlikely that any one database would contain all the information necessary to make a classification. Some databases specialise in aquatic toxicity and others in environmental fate. There is an obligation on the chemical supplier to make the necessary searches and checks to determine the extent and quality of the data available and to use it in assigning the appropriate hazard category.

## **G.2.5 Data quality**

**G.2.5.1** Data generated in accordance with standard international guidelines and with GLP are preferred over other types of data. However, classification could be based on the best available data. Thus, if no data is available which conforms to the quality standards of international guidelines and GLP, classification could still be made, provided that the data used is not considered invalid. To assist this process, the following quality-scoring guide for data has been developed:

- a) official data sources that have been validated by regulatory authorities, such as *EU Water Quality Monographs*, and *USEPA Water Quality Criteria*. However, no assumption should be made that these are the only data available. Due regard should be given to the date of the relevant report to ensure that the latest available data are considered;
- b) recognized international guidelines, for example OECD Guidelines, or national guidelines of equivalent quality;
- c) test results that, while not strictly according to a guideline as given in (a) and (b) above, follow accepted scientific principles and procedures and/or have been peer reviewed prior to publication. For such results, where all the experimental detail is not recorded, some expert judgement might be required to determine validity;
- d) test procedures that deviate significantly from standard guidelines and are considered as unreliable, should not be used in classification;
- e) QSAR data (see G.3.3.5, G.5.2.4.3, G.6.2 to G.6.4); and
- f) secondary sources such as handbooks, reviews, citations, etc. where the quality of the data cannot be directly evaluated but have sufficient detail to allow the quality to be assessed. In determining the acceptability of these data for the purposes of classification, due regard should be given to the difficulties in testing that might have affected data quality and the significance of the reported result in terms of the level of the hazard identified (see G.3.6.2.3).

**G.2.5.2** Classification could be made on incomplete and lower quality toxicity data, for example where data are not available on all three trophic levels. In such cases, the classification should be considered as "provisional" and subject to further information becoming available. In these circumstances, expert judgement is needed on the true level of hazard. Where good quality data are available for a particular species or taxa, this should be used in preference to any lower quality data that might also be available for that species or taxa. In the case of lower quality data consideration should be given to the difficulties that might have affected the likelihood of achieving a valid result. For example, the test details and experimental design might be critical to the assessment of the usability of some data, such as that from hydrolytically unstable chemicals, while less so for other chemicals (see G.3).

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**G.2.5.3** Normally, the identification of hazard, and hence the classification, is based on information obtained from testing of the substance in question. There are occasions, however, where difficulties in the testing or the outcomes do not conform to common sense. For example, some chemicals, although stable in a container, react rapidly (or slowly) in water giving rise to degradation products that have different properties than that of the parent substance. Where degradation is rapid, test data frequently define the hazard of the degradation products and these data are used for classification of the parent substance. However, where degradation is slower, it might be possible to test the parent substance and thus generate hazard data in the normal manner. The subsequent degradation product(s) should then be considered to determine whether an acute or a chronic hazard class apply. There might be occasions, however, when a substance degrades to give rise to a more hazardous product. In these circumstances, the hazard of the degradation product(s) and the rate at which they are formed under normal environmental conditions should be taken into account for the classification of the parent substance.

### **G.3 Aquatic toxicity**

#### **G.3.1 Introduction**

The identification and classification of substances as hazardous to the aquatic environment are based on the toxicity data for fish, crustacea, and algae/aquatic plants. These taxa are generally accepted as representative of aquatic fauna and flora for hazard identification. Since data on these particular taxa are readily available, the data are generally acceptable to regulatory authorities and the chemical industry. Information on the degradation and bioaccumulation behaviour of a substance is used to better delineate the aquatic hazards. Clauses G.3.2 to G.3.5 describe:

- a) appropriate tests for ecotoxicity;
- b) basic concepts in evaluating the data and using combinations of test results for classification;
- c) approaches for dealing with difficult substances; and
- d) interpretation of data quality.

#### **G.3.2 Description of tests**

##### **G.3.2.1 General**

**G.3.2.1.1** Toxicity data on fresh water species and marine species are considered as equivalent data. It should be noted, however, that some types of substances, for example ionizable organic chemicals or organometallic compounds might express different toxicities in freshwater and marine environments. The result showing the highest toxicity should be used for classification purposes.

**G.3.2.1.2** The GHS criteria for determining health and environmental hazards are test method neutral, allowing for different approaches as long as they are scientifically sound and validated according to international procedures and the criteria are already referred to in existing systems for the endpoints of concern and produce mutually acceptable data. According to the proposed system (OECD 1998):

"Acute toxicity would normally be determined using a fish 96 h  $LC_{50}$  (OECD Test 203 or equivalent), a crustacea species 48 h  $EC_{50}$  (OECD Test 202 or equivalent) and/or an algal species 72 or 96 h  $EC_{50}$  (OECD Test 201 or equivalent). These species are considered as surrogate for all aquatic

organisms and data on other species such as the duckweed *Lemna* may also be considered if the test methodology is suitable."

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**G.3.2.1.3** Chronic testing involves an exposure of a substances over longer periods of time and tests could run from days to a year, or more, depending on the reproductive cycle of the aquatic organism. Chronic tests are performed to assess certain endpoints relating to growth, survival, reproduction and development.

"Chronic toxicity data are less available than acute data and the range of testing procedures less standardized. Data generated according to the OECD Test 210 (Fish Early Life Stage), 202 Part 2 or 211 (Daphnia Reproduction) and 201 (Algal Growth Inhibition) can be accepted. Other validated and internationally accepted tests could also be used. The NOECs or other equivalent  $L(E)C_x$  should be used."

**G.3.2.1.4** Guidelines for conducting acceptable tests with fish, crustacea, and algae can be found in many sources (OECD, 1999; EPA, 1996; ASTM, 1999; ISO EU). The OECD monograph No. 11, *Detailed Review Paper on Aquatic Toxicity Testing for Industrial Chemicals and Pesticides*, is a good compilation of test methods performed in the marine environment and of sources for testing guidance. This document is also a source of appropriate test methodologies.

### **G.3.2.2 Toxicity tests on fish**

#### **G.3.2.2.1 Acute toxicity**

Acute toxicity testing on fish is generally performed with young juveniles of bodyweight 0,1 g to 5 g for a period of 96 h. The observational endpoint is mortality. Fish larger than this range or test durations shorter than 96 h (or both) are generally less sensitive. However, such test data could be used for classification, provided that no acceptable test data for fish of bodyweight 0,1 to 5 g over a test period of 96 h are available, or the results obtained with larger fish or a shorter test duration would lead to a more hazardous category. Tests consistent with OECD Test 203 (fish 96 h  $LC_{50}$ ) or any other internationally recognized test should be used for classification.

#### **G.3.2.2.2 Chronic toxicity**

Chronic or long-term toxicity testing on fish can be initiated with fertilized eggs, embryos, juveniles, or reproductively active adults. Tests consistent with the fish early life stage test (OECD Test 210), the fish life-cycle test (US EPA 850.1500), or equivalent, may be used. Durations could vary widely depending on the test purpose (from 7 d to over 200 d). Observational endpoints include hatching success, growth (length and weight changes), spawning success, and survival. Technically, OECD 210 is not a "chronic" test, but a sub-chronic test on sensitive life stages. However, it is widely accepted as a predictor of chronic toxicity and is used as such for purposes of classification in the harmonized system. Furthermore, data on fish early life stage toxicity are much more available than fish life cycle or reproduction studies.

### **G.3.2.3 Toxicity tests on crustacea**

#### **G.3.2.3.1 Acute toxicity**

Acute toxicity testing on crustacea generally begins with first instar juveniles. For daphnids, the test is performed over a period of 48 h. For other crustacea, such as mysids or others, a test period of 96 h is typical. The observational endpoint is mortality or immobilisation (unresponsive to gentle prodding) as a surrogate to mortality. Tests consistent with OECD Test 202 Part 1 (Daphnia acute), or USA-EPA OPPTS 850.1035 (Mysid acute toxicity), or any other internationally recognized test should be used for classification.

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### **G.3.2.3.2 Chronic toxicity**

Chronic toxicity testing on crustacea generally begins with first instar juveniles and continues through maturation and reproduction. For daphnids, a test period of 21 d is sufficient for maturation and the production of 3 broods. For mysids, a test period of 28 d is necessary. Observational endpoints include the time to the production of the first brood, the number of offspring produced per female, growth, and survival. Tests consistent with OECD Test 202 Part 2 (Daphnia reproduction) or US-EPA 850.1350 (Mysid chronic) or any other internationally recognized test should be used for classification.

### **G.3.2.4 Toxicity tests on algae/aquatic plants**

#### **G.3.2.4.1 Algae**

Algae are cultured and exposed to the test substance in a nutrient-enriched medium. Tests consistent with OECD Test 201 (Algal growth inhibition) should be used. Standard test methods employ a cell density in the inoculum in order to ensure exponential growth through the test, usually over a 3 d to 4 d duration.

The algal test is a short-term test and, although it provides both acute and chronic endpoints, only the acute  $EC_{50}$  results should be used for classification in the harmonized system. The preferred observational endpoint is algal growth rate inhibition as it is independent of the test design, whereas biomass depends on growth rate of the test species, test duration and other elements of test design. If the endpoint is reported only as reduction in biomass or the endpoint is not specified, then this value may be interpreted as an equivalent endpoint.

#### **G.3.2.4.2 Aquatic macrophytes**

The most commonly used vascular plants for aquatic toxicity tests are duckweeds (*Lemna gibba* and *Lemna minor*). The Lemna test is a short-term test and, although it provides both acute and sub-chronic endpoints, only the acute toxicity ( $EC_{50}$ ) is used for classification in the harmonized system. The tests last for up to 14 d and are performed in nutrient enriched media similar to that used for algae. However, the strength of the nutrient media may be increased. The observational endpoint is based on change in the number of fronds produced. Tests consistent with US-EPA 850.4400 (Aquatic plant toxicity, Lemna), or any other internationally recognized test should be used.

## **G.3.3 Aquatic toxicity concepts**

### **G.3.3.1 Acute toxicity**

**G.3.3.1.1** For purposes of classification acute toxicity refers to the intrinsic property of a substance to be injurious to an organism in a short-term exposure to that substance. Acute toxicity is generally expressed in terms of a concentration which is lethal to 50 % of the test organisms ( $LC_{50}$ ), causes a measurable adverse effect to 50 % of the test organisms (e.g. immobilisation of daphnids), or leads to a 50 % reduction in test (treated) organism responses from control (untreated) organism responses (e.g. growth rate in algae).

**G.3.3.1.2** A substances with an acute toxicity of less than 1 mg/L is regarded as very toxic. The handling, use, or discharge into the environment of such a substance poses a high degree of hazard and it is classified in chronic and/or acute category 1. An acute toxicity of less than 1 mg/L may be expressed in decimal fractions. A substance with an acute toxicity of 1mg/L to 10 mg/L is classified in acute category 2. A substance with an acute toxicity of 10 mg/L to 100 mg/L is classified in acute category 3 and those over 100 mg/L are regarded as practically non-toxic.



### **G.3.3.2 Chronic toxicity**

**G.3.3.2.1** For purposes of classification, chronic toxicity refers to the potential or actual properties of a substance to cause adverse effects to aquatic organisms during exposures that are determined in relation to the life-cycle of the organism. Such chronic effects usually include a range of sub-lethal endpoints and are generally expressed in terms of a No Observable Effect Concentration (NOEC), or an equivalent  $EC_x$ . Endpoints typically include survival, growth and/or reproduction. Chronic toxicity exposure durations vary widely depending on test endpoint measured and test species used.

**G.3.3.2.2** Chronic toxicity data are less common in certain sectors than acute data for classification schemes. The potential of a substance to cause chronic toxicity is identified by appropriate combinations of acute toxicity, lack of degradability, and/or the potential or actual bioaccumulation. Where such data exist and show long-term NOECs > 1 mg/L, this should be taken into account for a decision whether classification based on the acute toxicity data applies. In this context, a chronic classification could be disregarded when it is demonstrated that the NOEC used would be suitable in removing the concern for all taxa that resulted in classification. This could be achieved by a long-term NOEC > 1 mg/L for the most sensitive species identified by the acute toxicity. Thus, if a classification has been applied based on a fish acute toxicity ( $LC_{50}$ ), it would generally not be possible to remove this classification by using a long-term NOEC from an invertebrate toxicity test. In this case, the NOEC should be derived from a long-term fish test of the same species, or a test of equivalent or greater sensitivity. Furthermore, if classification has resulted from the acute toxicity to more than one taxa, NOECs > 1 mg/L from each taxa need to be demonstrated. In case of classification of a substance as chronic category 4, it is sufficient to demonstrate that NOECs are greater than the water solubility of the substances under consideration.

**G.3.3.2.3** Testing with algae/Lemna cannot be used for the de-classification of chemicals because

- a) algae and Lemna tests are not long-term studies,
- b) the acute to chronic ratio is generally narrow, and
- c) the endpoints are more consistent with the end points for other organisms.

However, where classification is applied solely due to the acute toxicity ( $L(E)C_{50}$ ) observed in single algae/aquatic plant tests, but there is evidence from a range of other algae tests that the chronic toxicity (NOECs) for this taxonomic group is above 1 mg/L, this evidence could be used to consider declassification. At present this approach cannot be applied to aquatic plants since no standardized chronic toxicity tests have been developed.

**G.3.3.2.4** The GHS is intended to contain a specific value of chronic toxicity below which substances would be classified as chronically toxic, but the criteria are not yet set.

### **G.3.3.3 Exposure regimes**

Four types of exposure conditions, namely static, static-renewal (semi-static), re-circulation and flow-through, are employed in both acute and chronic tests and in both freshwater and saltwater media. The choice for the test type to be used usually depends on test substance characteristics, test duration, test species, and regulatory requirements.

### **G.3.3.4 Test media for algae**

Algal tests are performed in nutrient-enriched media and the use of one common constituent; EDTA, or other chelating agents, should be considered carefully. When testing the toxicity of organic chemicals, trace amounts of a chelating agent like EDTA are needed to complex micronutrients in the culture medium; if omitted, algal growth could be significantly reduced and compromise test utility. However, chelating agents might reduce the observed toxicity of metal test substances. It is therefore desirable

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that, for metal compounds, test data with a high concentration of chelating agents or tests (or both), with a stoichiometric excess of a chelating agent relative to iron be critically evaluated. A free chelating agent might mask heavy metal toxicity considerably, in particular with strong chelating agents such as EDTA. However, in the absence of available iron in the medium, the growth of algae could become iron limited. Consequently, data from tests with no, or with reduced, iron and EDTA should be treated with caution.

### **G.3.3.5 Use of QSARs**

For purposes of classification, and in the absence of experimental data, QSARs can be relied upon to provide predictions of acute toxicity for fish, daphnia, and algae for non-electrolyte, non-electrophilic, and otherwise non-reactive substances (see G.6 on the use of QSARs). However, the classification of substances, for example, organophosphates that operate by means of special mechanisms such as functional groups that interact with biological receptors, or form sulfhydryl bonds with cellular proteins, remains problematic. Reliable QSARs have been derived for chemicals acting by a basic narcosis mechanism. These chemicals are non-electrolytes of low reactivity such as hydrocarbons, alcohols, ketones and certain aliphatic chlorinated hydrocarbons that produce their biological effects as a function of their partition coefficients. All organic chemicals can produce narcosis. However, if the chemical is an electrolyte or contains specific functional groups leading to non-narcotic mechanisms as well, calculations of toxicity based on the partition coefficient alone would severely underestimate the toxicity. QSARs for acute aquatic toxicity of parent compounds cannot be used to predict the effects of toxic metabolites or degraded substances when these arise after a longer time period than the duration of acute tests.

### **G.3.4 Weight of evidence**

**G.3.4.1** The best quality data, preferably based on primary data sources, should be used as the fundamental basis for classification. Furthermore, test conditions should be clearly and comprehensively articulated.

**G.3.4.2** Where multiple studies for a taxonomic group are available, a decision should be taken on the study that is the most sensitive and of highest quality. Judgements should be made on a case-by-case basis as to whether a non-GLP study with a more sensitive observation should be used in lieu of a GLP study. Results indicating high toxicity from tests performed in accordance with non-standard or non-GLP guidelines could be used for classification, whereas studies that demonstrate negligible toxicity require more careful consideration. Substances, that are difficult to test, might yield apparent results that are more or less severe than the true toxicity and expert judgement would be needed for classification in these cases.

**G.3.4.3** Where more than one acceptable test is available for the same taxonomic group, the most sensitive (the one with the lowest  $L(E)C_{50}$  or NOEC) is generally used for classification. However, this must be dealt with on a case-by-case basis. When larger data sets (4 or more values) are available for the same species, the geometric mean of toxicity values may be used as the representative toxicity value for that species. In estimating a mean value, it is not advisable to combine tests of different species within a taxa group or in different life stages or tested under different conditions or duration.

### **G.3.5 Substances difficult to test**

#### **G.3.5.1 General**

**G.3.5.1.1** Valid aquatic toxicity tests require dissolution of the test substance in the water media under the test conditions recommended. In addition, a bio-available exposure concentration should be maintained for the duration of the test. Some chemical substances are difficult to test in aquatic systems and guidance has been developed to assist in the testing of these substances (see DoE 1996, ECETOC 1996 and US EPA 1996).



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**G.3.5.1.2** However, test data exist that have test methodologies that, while not in conformity with what is considered best practice today, can still yield information suitable for application of the classification criteria. Such data require special guidance on interpretation, although ultimately, expert judgement is needed in determining data validity. Substances difficult to test might be poorly soluble, volatile, or subject to rapid degradation due to such processes as photo-transformation, hydrolysis, oxidation, or biotic degradation. When testing algae, coloured materials interfere with the test endpoint by attenuating the light needed for cell growth. Similarly, substances tested as cloudy dispersions above solubility could give rise to false toxicity measurements. Loading of the water column with test material can be an issue for particulates or solids such as metals. Petroleum distillate fractions might also pose loading problems as well as difficult interpretational problems for the appropriate concentrations in determining  $L(E)C_{50}$  values. Common properties of substances that are likely to pose difficulties during testing are given in G.3.5.2 to G.3.5.6.

**G.3.5.1.3** It is desirable to have stabilized and analytically measured test concentrations for the classification of organic compounds. Although measured concentrations are preferred, classification could be based on nominal concentration studies when they provide the only valid data available under certain circumstances. If the material is likely to substantially degrade or otherwise be lost from the water column, care should be taken with data interpretation and the loss of the toxicant during the test, if relevant and possible, should be taken into account for classification. Additionally, metals present their own set of difficulties and are discussed separately. Table G.1 lists several properties of difficult to test substances and their relevance for classification.

**G.3.5.1.4** The actual test concentration is likely to be less than the nominal or expected test concentration under most difficult to test conditions. Where toxicities ( $L(E)C_{50}$ ) are estimated to be less than 1 mg/L for a difficult to test substance, one can be fairly confident the classification in the acute category 1 (and chronic category 1, if appropriate) is warranted. However, if the estimated toxicity is greater than 1 mg/L, the estimated toxicity is likely to under-represent the toxicity. In these circumstances, expert judgement is needed to determine the acceptability of a test with a difficult to test substance for use in classification. Where the nature of the testing difficulty is believed to have a significant influence on the actual test concentration when toxicity is estimated to be greater than 1 mg/L and the test concentration is not measured, then the test should be used with due caution in classification.

### **G.3.5.2 Stability**

If the concentration of the chemical under test is expected to fall below 80 % of nominal, exposure regimes that provide for renewal of the test material are required in order to render the test valid. Semi-static or flow-through conditions are preferred. Special problems arise, therefore, with respect to testing on algae where the standard guidelines include static tests to be conducted. While alternative exposure regimes are possible for crustacea and fish, these tests are frequently conducted on static conditions as included in the internationally agreed guidelines. In these tests, a certain level of degradation as well as other relevant factors has to be tolerated and appropriate account should be taken in calculations of toxic concentrations. Some approaches on how this can be dealt with are covered in G.3.5.7. Where degradation occurs, it is also important to consider the influence of the toxicity of the degradation products on the recorded toxicity in the test. Expert judgement needs to be exercised when deciding if the data could be used for classification.

### **G.3.5.3 Degradation**

When a compound breaks down or degrades under test conditions, expert judgement should be used in calculating toxicity for classification, including consideration of known or likely breakdown products. Concentrations of the parent material and all significant toxic degradation products are desirable. If the degradation products are expected to be relatively non-toxic, renewable exposure regimes are desirable in order to ensure that levels of the parent compounds are maintained.

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### **G.3.5.4 Saturation**

The classification of single component substances should be based only on toxic responses observed in the soluble range, and not on total chemical loading above solubility. Frequently, data are available which indicate toxicity at levels in excess of water solubility and, while these data will often be regarded as not valid, some interpretation might be possible. These problems generally apply when testing poorly soluble substances, and guidance on how to interpret such data is included in G.3.6.

### **G.3.5.5 Perturbation of test media**

Special provisions might be needed to ensure dissolution of difficult to test substances. Such measures should not lead to significant changes in the test media when such changes are likely to lead to an increase or decrease in the apparent toxicity and hence the classification level of the test substance.

### **G.3.5.6 Complex substances**

Many substances covered by the classification scheme are in fact mixtures, for which measurement of exposure concentrations is difficult, and in some cases impossible. Substances such as petroleum distillate fractions, polymers, substances with significant levels of impurities, etc. could pose special problems since the toxic concentration is difficult to define and impossible to verify. Typical testing procedures often rely on the formation of a Water Soluble Fraction (WSF) or a Water Accommodated Fraction (WAF) and data are reported in terms of loading rates. These data may be used in applying the classification criteria.

### **G.3.5.7 Unstable substances**

**G.3.5.7.1** Ideally, test procedures should minimize the impact of instability in the test media. However, sometimes it is almost impossible to maintain a concentration throughout the test. Common causes of such instability are oxidation, hydrolysis, photo-degradation and biodegradation. While photo-degradation and biodegradation can more readily be controlled, such controls are frequently absent in many existing test methods. Nevertheless, for some tests, and particularly for acute and chronic fish toxicity testing, a choice of exposure regimes is available to help minimize losses due to instability. This should be taken into account in deciding on the test data validity.

**G.3.5.7.2** Where instability is a factor in determining the level of exposure during the test, an essential prerequisite for data interpretation is the existence of measured exposure concentrations at suitable time points throughout the test. In the absence of analytically measured concentrations, at least at the start and the end of a test, no valid interpretation can be made and the test should be considered as invalid for classification purposes. Where measured data are available, the following practical rules should be considered by way of guidance in interpretation:

- a) calculation of the acute toxicity  $L(E)C_{50}$  for daphnia and algal based on the geometric mean of the start and the end of test concentrations. Where the concentration at the end of the test is below the analytical detection limit, such a concentration is considered to be half that of the detection limit;
- b) concentrations at the start and the end of media renewal periods (as may be available for the semi-static tests), should be used to calculate the geometric mean for each renewal period and the mean exposure over the whole exposure period;
- c) toxicity ( $L(E)C_{50}$ ) attributed to a degradation breakdown product could be calculated back to the parent substance based on the geometric mean of the degradation product concentration; and
- d) similar principles may be applied to measured data in chronic toxicity testing.

### **G.3.5.8 Poorly soluble substances**

**G.3.5.8.1** A poorly soluble substance is a substance with a water solubility of  $< 1$  mg/L. Such a substance does not readily dissolve in the test media, and the concentration dissolved is often difficult to determine at such low levels. For many substances, the true solubility in the test media is unknown, and is often recorded as "less than the detection limit in purified water". Nevertheless, such substances might still be hazardous to the environment. If no toxicity is found, expert judgement should be applied as to whether the result could be considered valid for classification. Judgement should err on the side of caution and should not underestimate the hazard.

**G.3.5.8.2** Preference should be given to data obtained from tests with dissolution techniques that accurately measure the dissolved concentrations within the range of water solubility. Often the toxicity levels of older recorded data are in excess of the water solubility, or the dissolved levels are below the detection limit of the analytical method. In both these instances it would not be possible to verify the actual exposure concentrations using measured data. However, if this is the only data available on which to classify, the following practical rules could be considered by way of general guidance where:

- a) the acute toxicity is recorded at levels in excess of the water solubility, then the  $L(E)C_{50}$  applied for classification can be taken as equal to, or below, the measured water solubility. In such circumstances it is likely that chronic category 1 and/or acute category 1 apply. Due attention should be paid to the possibility that excess insoluble substance might give rise to physical effects on the test organisms. Where this is considered the likely cause of the effects observed, the test should be considered as invalid for classification purposes;
- b) no acute toxicity is recorded at levels in excess of the water solubility, the  $L(E)C_{50}$  applied for classification purposes should be taken as greater than the measured water solubility. In such circumstances, consideration should be given to whether the chronic category 4 should apply. In making a decision that the substance shows no acute toxicity, due account should be taken of the techniques used to achieve the maximum dissolved concentrations. Where these are not considered as adequate, the test should be considered as invalid for classification purposes;
- c) the water solubility is below the detection limit of the analytical method for a substance and the acute toxicity is recorded, then the  $L(E)C_{50}$  applied for classification purposes should be taken as less than the analytical detection limit. Where no toxicity is observed, the  $L(E)C_{50}$  applied for classification purposes should be taken as greater than the water solubility. Due consideration should also be given to the quality of data (see G.2.5); and
- d) chronic toxicity data are available, the same general rules apply. Only data showing no effects at the water solubility limit, or a water solubility  $> 1$  mg/L, need to be considered. Again, where data cannot be validated by means of measured concentrations, the techniques used to achieve the maximum dissolved concentrations should be considered as appropriate.

### **G.3.5.9 Other factors contributing to concentration loss**

#### **G.3.5.9.1 General**

Factors other than those given in G.3.5.1 to G.3.5.8 could also contribute to a loss of concentration. While some could be avoided by correct study design, interpretation of the contribution of the factors given in G.3.5.9.2 to G.3.5.9.4 is, from time to time, necessary.

#### **G.3.5.9.2 Sedimentation**

Sedimentation occurs during a test for a number of reasons. A common explanation is that the substance has not truly dissolved despite the apparent absence of particulates, and agglomeration occurs during the test leading to precipitation. In these circumstances, the  $L(E)C_{50}$  applied for

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classification purposes should be based on the end of test concentrations. Precipitation occurring through reaction with the media is regarded as instability (see G.3.5.7).

### **G.3.5.9.3 Adsorption**

Adsorption occurs where a substance has the ability to condense or hold molecules of other substances on its surface. Typically, substances of high adsorption characteristics have high  $\log K_{ow}$  values. Adsorption is indicated by a rapid loss of concentration and is best characterized by the end of test concentrations.

### **G.3.5.9.4 Bioaccumulation**

Loss in concentration might occur through the bioaccumulation (see 3.1.8) of a substance into the test organisms. This is particularly important where the water solubility is low and  $\log K_{ow}$  correspondingly high. In such a case, the  $L(E)C_{50}$  applied for classification purposes should be based on the geometric mean of the start and end of test concentrations.

### **G.3.5.10 Perturbation of the test media**

**G.3.5.10.1** Strong acids and bases appear to be toxic because of their ability to alter the pH of test media. Changes of the pH in aquatic systems are normally prevented by buffer systems in the test medium. If no data are available on a salt, it should be classified in the same way as the anion or cation, that is, as the ion that receives the most stringent classification. If the effect concentration is related to only one of the ions, the classification of the salt should take the molecular mass difference into consideration and correct the effect concentration by multiplying the concentration with the ratio molecular mass of the salt: molecular mass of the ion.

**G.3.5.10.2** Polymers are typically not available in aquatic systems. Dispersible polymers and other high molecular mass materials could perturb the test system and interfere with the uptake of oxygen, thus giving rise to mechanical or secondary effects. These factors need to be taken into account when considering data from these substances. Many polymers behave like complex substances, having a significant low molecular mass fraction that leach from the bulk polymer (also see G.3.5.11.2).

### **G.3.5.11 Complex substances**

**G.3.5.11.1** A complex substance is characterized by a range of chemical structures, frequently in a homologous series, but covering a wide range of water-soluble and other physico-chemical characteristics (also see G.3.5.6). On the addition of a complex substance to water, equilibrium is reached between the soluble and insoluble fractions that are characteristic of the loading of the substance. For this reason, complex substances are usually tested as a water soluble fraction (WSF) or water accommodated fraction (WAF), and the  $L(E)C_{50}$  based on the loading or nominal concentrations. Analytical support data are not normally available since the dissolved fraction would be a complex mixture of components. The toxicity parameter is sometimes referred to as  $LL_{50}$ , related to the lethal loading level. This loading level from the WSF or WAF may be used directly in the classification criteria.

**G.3.5.11.2** A polymer represents a special kind of complex substance that requires consideration of the polymer type and the dissolution/dispersal behaviour. A polymer might dissolve as such without change, (true solubility related to particle size), be dispersible, or portions consisting of low molecular mass fractions might go into solution. In the latter case, the testing of a polymer determines the ability of low molecular mass material to leach from the bulk polymer, and the toxicity of the leached out fraction. A polymer could thus be considered in the same way as a complex mixture in that a loading of polymer is best characterized by the resultant leached out fraction, and hence the toxicity can be related to this loading.

**Table G.1 — Classification of difficult substances**

1	2	3
Property	Nature of difficulty	Relevance for classification
Poorly water soluble	To achieve/maintain the required exposure concentration and to determine the exposure concentration.	When toxic responses are observed above apparent solubility, expert judgement is required to confirm whether effects are due to chemical toxicity or a physical effect. If no effects are observed, it should be demonstrated that full, saturated dissolution has been achieved.
Toxic at low concentrations	To achieving/maintain required exposure concentration and to determine the exposure concentration.	Classification based on toxicity < 1 mg/L.
Volatile	Maintain and measure exposure concentration.	Classification should be based on reliable measurement of concentrations.
Photo-degradable	To maintain the exposure concentration and to determine the toxicity of breakdown products.	Classification requires expert judgement based on measured concentrations. Toxicity of significant breakdown products should be characterized.
Hydrolytically unstable	To maintain the exposure concentration and to determine the toxicity of breakdown products.  Comparison of degradation half-lives to the exposure regimen used in testing.	Classification requires expert judgement based on measured concentrations and needs to address the toxicity of significant breakdown products.
Oxidizing	To achieve, maintain and measure the exposure concentration. To determine the toxicity of modified chemical structures or breakdown products.  Comparison of degradation half-lives to the exposure regimen used in testing.	Classification requires expert judgement based on measured concentrations and needs to address the toxicity of significant breakdown products.
Subject to corrosion/transformation (refers to metals/metal compounds)	To achieve, maintain and measure the exposure concentration. Comparison of partitioning from the water column half-lives to the exposure regimen used in testing.	Classification requires expert judgement based on measured concentrations and needs to address the toxicity of significant breakdown products.
Biodegradable	To maintain the exposure concentrations and to determine the toxicity of breakdown products.  Comparison of degradation half-lives to the exposure regimen used in testing.	Classification requires expert judgement based on measured concentrations and needs to address the toxicity of significant breakdown products.
Adsorbing	To maintain the exposure concentration and to analyse the exposure. Determine toxicity mitigation due to reduced availability of test substance.	Classification should be based on measured concentration of available material.
Chelating	To distinguishing between chelated fraction and non-chelated fraction in the test media.	Classification should be based on measured concentration of bio-available material.

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**Table G.1** (*concluded*)

1	2	3
Property	Nature of difficulty	Relevance for classification
Coloured	Light attenuation (an algal problem).	Classification should distinguish toxic effects from reduced growth due to light attenuation.
Hydrophobic	Maintaining constant exposure concentrations.	Classification should use measured concentration.
Ionised	Maintaining exposure concentrations. Toxicity of breakdown products. Comparison of degradation half-lives to exposure regime used in testing.	Classification requires expert judgement based on measured concentrations and needs to address the toxicity of significant breakdown products.
Multi-component	Preparing representative test batches.	Considered same as complex mixture.

### G.3.6 Interpretation of data quality

#### G.3.6.1 Standardization

The goal of test standardization and international harmonization is to reduce test variability and improve precision, reproducibility, and consistency of test results. Factors that influence the results of toxicity tests with aquatic organisms are characteristics of the test water, experimental design, chemical characteristics of the test material and biological characteristics of the test organisms. Standardized test procedures should be used in conducting aquatic toxicity tests to reduce the influence of these sources of extraneous variability.

#### G.3.6.2 Data hierarchies

**G.3.6.2.1** The classification of substances hazardous to the aquatic environment should be based on primary data of good quality. Preference is given to data conforming to OECD Test Guidelines or equivalent tests and Good Laboratory Practice (GLP). However, results of tests performed by means of widely recognized international or national methods, or their equivalent, could also be used, for example ISO or ASTM methods. Data from tests that appear to conform to accepted guidelines but lack provisions for GLP may be used in the absence of pertinent GLP data.

**G.3.6.2.2** Pedersen *et al* (1995) provides a data quality-scoring system that is compatible with many others in current use, including that used by the US-EPA for its AQUIRE database (see also Mensink *et al.* (1995)). The data quality scoring system includes a ranking scheme for reliability that could be used as a model for classification under the harmonized system. The first three levels of data described by Pedersen are preferred.

**G.3.6.2.3** Data from primary sources should be used for classification under the harmonized system. Reviews from national authorities and expert panels could be used as long as the reviews are based on primary sources, for example reviews compiled by a well-recognized group such as GESAMP. Such reviews should include summaries of test conditions that are sufficiently detailed for weight of evidence and classification decisions to be made on.

**G.3.6.2.4** In the absence of empirical test data, validated Quantitative Structure Activity Relationships (QSARs) for aquatic toxicity may be used. Test data always take precedence over QSAR predictions, provided that the test data are valid.



## **G.4 Degradation**

### **G.4.1 Introduction**

**G.4.1.1** Degradability (see 3.1.23) is one of the important intrinsic properties of chemical substances that determine their potential environmental hazard. Non-degradable substances persist in the environment and might have a potential for causing long-term adverse effects on biota. On the other hand, degradable substances could be removed in the sewers, in sewage treatment plants or in the environment.

**G.4.1.2** The degree of degradation depends not only on the intrinsic properties of the molecule but also on the actual conditions in the receiving environmental compartment, for example reduction-oxidation potential, pH, presence of suitable micro-organisms, concentration of the substances and occurrence and concentration of other substrates. Therefore, interpretation of the degradation properties in an aquatic hazard classification context requires detailed criteria that balance the intrinsic properties of the substance and the prevailing environmental conditions into a concluding statement on the potential for long-term adverse effects. The types of degradation data to be considered are biodegradability, simulation for transformation in water, aquatic sediment and soil, BOD<sub>5</sub>/COD and techniques for estimation of rapid degradability in the aquatic environment. Additional data that should be considered are anaerobic degradability, inherent biodegradability, sewage treatment plant simulation test data, abiotic transformation data such as hydrolysis and photolysis, removal process such as volatilisation and data obtained from field investigations and monitoring studies.

**G.4.1.3** The concept of degradability as applied to organic compounds has limited or no meaning for inorganic compounds and metals as they are transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Therefore, only organic substances and organo-metals are taken into account for the classification of substances hazardous to the aquatic environment.

### **G.4.2 Interpretation of degradability data**

#### **G.4.2.1 Rapid degradability**

Classification of a substance as readily degradable is normally based on existing data of their environmental properties. It is seldom that test data are produced with the main purpose of facilitating a classification. Often a diverse range of test data is available that does not necessarily fit directly with the classification criteria and therefore guidance for the interpretation of existing data are given in G.4.2.2 to G.4.2.4.

#### **G.4.2.2 Ready biodegradability**

##### **G.4.2.2.1 General**

An organic substance that degrades to a level higher than the pass level in a standard OECD ready biodegradability test or in a similar test should be considered readily biodegradable and consequently also rapidly degradable (see OECD Test 301). Many test data quoted in literature, do not specify all the conditions that should be evaluated to demonstrate whether or not the test fulfils the requirements of a ready biodegradability test and expert judgement is therefore needed as regards the validity of the data.

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### **G.4.2.2.2 Concentration of test substance**

Relatively high concentrations (2-100 mg/L) of test substance are used in the ready biodegradability tests of the OECD. A substance might, however, be toxic to the inocula at such high concentrations causing a low degradation in the tests although the substance might be rapidly degradable at lower non-toxic concentrations (see OECD Test 209, ISO 9509 and ISO 11348) When it is likely that inhibition is the reason for a substance being not readily degradable, results from a test employing lower non-toxic concentrations of the test substance should be used when available. Such test results could, on a case-by-case basis, be considered in relation to the classification criteria for rapid degradation. However, surface water degradation test data with environmentally realistic microbial biomass and non-toxic realistic low concentration of the test substance are preferred.

### **G.4.2.2.3 Time window**

The harmonized criteria include a requirement for ready biodegradability to be achieved within 10 d irrespective of the test method used. This is not in line with OECD Test 301 (see also OECD Test 301C), and according to OECD Test 301D, a 14 d time window could be used when measurements have not been made after 10 d. Limited information is available in references of biodegradation tests. Thus, as a pragmatic approach the percentage of degradation reached after 28 d could be used for assessment of ready biodegradability when no information on the 10 d time window is available. However, this is only acceptable for existing test data and data from tests where the 10d time window does not apply.

### **G.4.2.3 BOD<sub>5</sub>/COD**

The BOD<sub>5</sub> test is a traditional biodegradation test that has been replaced by the ready biodegradability tests and should no longer be performed for assessment of the ready biodegradability of substances. Information on the 5 d biochemical oxygen demand (BOD<sub>5</sub>) may only be used for classification purposes when no other measured degradability data are available. Thus, priority should be given to data from ready biodegradability tests and from simulation studies regarding degradability in the aquatic environment. Where the chemical structure of a substance is known, the theoretical oxygen demand (ThOD) should be calculated and this value used instead of the chemical oxygen demand (COD).

### **G.4.2.4 Other convincing scientific evidence**

#### **G.4.2.4.1 General**

**G.4.2.4.1.1** Rapid degradation in the aquatic environment might be demonstrated by other data than that given in 11.2.4.1(a) and (b), such as biotic or abiotic degradation (or both). Data on primary degradation may only be used where it is demonstrated that the degradation products shall not be classified as hazardous to the aquatic environment, that is, that they do not fulfil the classification criteria.

**G.4.2.4.1.2** Compliance with 11.2.4.1(c) requires that the substance be degraded in the aquatic environment to a level greater than 70 % within a 28 d period. If first-order kinetics were assumed, which is reasonable at the low substance concentrations prevailing in most aquatic environments, the degradation rate will be relatively constant for the 28 d period. Thus, the degradation requirement of an average degradation rate constant, of  $k > -(\ln 0,3 - \ln 1)/28 = 0,043/\text{d}$  would be complied with (see OECD Test 302B and OECD Test 302C). This corresponds to a degradation half-life of  $t_{1/2} < \ln 2/0,043 = 16 \text{ d}$ .



**G.4.2.4.1.3** Degradation processes are temperature dependent and this should be taken into account when assessing degradation in the environment. Data from studies at environmentally realistic temperatures should be used for the evaluation. When data from studies performed at different temperatures need to be compared, the traditional Q10 approach could be used, that is, that the degradation rate is halved when the temperature decreases by 10 °C.

**G.4.2.4.1.4** The evaluation of degradation data should be conducted on a case-by-case basis by expert judgement. However, guidance on the interpretation of various types of data for demonstrating rapid degradation in the aquatic environment is given in G.4.2.4.2 to G.4.2.4.12. In general, only data from aquatic biodegradation simulation tests are considered directly applicable but simulation test data from other environmental compartments could be considered as well, provided that such data are scientifically judged.

#### **G.4.2.4.2 Aquatic simulation tests**

Aquatic simulation tests are conducted in a laboratory by simulating environmental conditions and employing natural specimens as inoculum. Results of aquatic simulation tests could be used directly for classification purposes, provided that the following environmental conditions in surface waters are simulated:

- a) substance concentration for the general aquatic environment (often in the low µg/L range);
- b) inoculum from a relevant aquatic environment;
- c) concentration of inoculum ( $10^3$  to  $10^6$  cells/mL);
- d) temperature, for example, 5 °C to 25 °C; and
- e) ultimate degradation (i.e. the rate at which the substance in question mineralises or the individual degradation rates of the total biodegradation pathway).

A substance that, under the above-mentioned conditions, degrades at least 70 % under the above-mentioned conditions within 28 d (that is, a half-life of less than 16 d) is considered rapidly degradable.

#### **G.4.2.4.3 Field investigations**

Field investigations or mesocosm experiments where fate or effects of chemicals in environments (or both), or environmental enclosures are investigated could be considered for the assessment of the potential for a rapid degradation together with laboratory simulation tests. However, it requires that ultimate degradation be demonstrated. This could be achieved with the preparation of mass balances showing that no non-degradable intermediates are formed and taking fractions into account that are removed from the aqueous system due to other processes such as sorption to sediment or volatilisation from the aquatic environment.

#### **G.4.2.4.4 Monitoring data**

Monitoring data demonstrate the removal of contaminants from the aquatic environment and should only be used as supporting evidence for demonstration of persistence in the aquatic environment or of rapid degradation. Such data are, however, very difficult to use for classification purposes and before use it should be considered whether:

- a) the removal is a result of degradation, or whether it is a result of other processes such as dilution or distribution between compartments (sorption, volatilisation); and
- b) the formation of non-degradable intermediates are excluded.

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Only when it can be demonstrated that removal as a result of ultimate degradation fulfils the criteria for rapid degradability, such data could be considered for classification purposes.

### **G.4.2.4.5 Inherent biodegradability tests**

A substance that degrades more than 70 % in tests for inherent biodegradability (see OECD Test 302) has the potential for ultimate biodegradation. However, because of the optimum conditions in these tests, the rapid biodegradability of inherently biodegradable substances in the environment cannot be assumed. The optimum conditions in inherent biodegradability tests stimulate adaptation of the micro-organisms and consequently increase the biodegradation potential compared to natural environments. Therefore, positive results in general should not be interpreted as evidence for rapid degradation in the environment.

### **G.4.2.4.6 Sewage treatment plant simulation tests**

Results from tests simulating the conditions in a sewage treatment plant (STP) (see OECD Test 303) cannot be used for the assessment of degradation in the aquatic environment for the following reasons:

- a) microbial biomass in a STP is significantly different from the biomass in the environment;
- b) composition of substrates is considerably different; and
- c) presence of rapidly mineralised organic matter in waste water facilitates degradation of the test substance by co-metabolism.

### **G.4.2.4.7 Soil and sediment degradation data**

More or less the same degradation rates are found in soil and in surface water for many non-sorbed (non-lipophilic) substances. A lower degradation rate for lipophilic substances generally occur in soil than in water due to partial immobilisation caused by sorption. Thus, when a substance has degraded rapidly in a soil simulation study, it is most likely also rapidly degradable in the aquatic environment. An experimentally determined rapid degradation in soil should therefore be sufficiently documented for rapid degradation in surface waters when:

- a) no pre-exposure (pre-adaptation) of the soil micro-organisms has taken place;
- b) an environmentally realistic concentration of substance is tested; and
- c) the substance is ultimately degraded within 28 d with a half-life of less than 16 d (corresponding to a degradation rate of more than 0,043/d).

The same argumentation is considered valid for data on degradation in sediment under aerobic conditions.

### **G.4.2.4.8 Anaerobic degradation data**

Anaerobic degradation data cannot be used for rapid degradability because the aquatic environment is generally regarded as the aerobic compartment where the aquatic organisms, such as those employed for aquatic hazard classification, live.

#### **G.4.2.4.9 Hydrolysis**

**G.4.2.4.9.1** Data on hydrolysis (see OECD Test 111) could be considered for classification purposes when the longest half-life ( $t_{1/2}$ ), determined within the pH range 4 to 9, is shorter than 16 d. However, hydrolysis is not an ultimate degradation and various intermediate degradation products might be formed, some of which may be only slowly degradable. Data from hydrolysis studies could be considered provided that it can be satisfactorily demonstrated that the hydrolysis products formed do not fulfil the criteria for classification as hazardous for the aquatic environment.

**G.4.2.4.9.2** Hydrolysis is regarded as part of the degradation process when a substance is quickly hydrolysed (for example,  $t_{1/2}$  is less than a few days) since hydrolysis might be the initial transformation process in biodegradation.

#### **G.4.2.4.10 Photochemical degradation**

Information on photochemical degradation is unreliable for classification purposes because of the following reasons:

- a) the actual degree of photochemical degradation in the aquatic environment depends on local conditions, for example water depth, suspended solids and turbidity;
- b) the hazard of the degradation products is usually not known; and
- c) sufficient information is seldom available for a thorough evaluation based on photochemical degradation.

#### **G.4.2.4.11 Estimation of degradation**

**G.4.2.4.11.1** Certain QSARs (see 11.2.7) have been developed for the prediction of an approximate hydrolysis half-life. However, they should only be considered when no experimental data are available. Care should be taken when using a hydrolysis half-life for classification purposes since it is not an ultimate degradation (see G.4.2.4.9). Furthermore, the QSARs developed have a rather limited applicability and are only able to predict the potential for hydrolysis on a limited number of chemical classes. For example, the QSAR program HYDROWIN (version 1.67, Syracuse Research Corporation) is only able to predict the potential for hydrolysis on less than a fifth of the existing EU substances that have a defined (precise) molecular structure.

**G.4.2.4.11.2** As yet, no quantitative estimation method (QSAR) for the degree of biodegradability of organic substances is sufficiently accurate to predict rapid degradation. However, results from such methods could be used to predict that a substance is not rapidly degradable. For example, a substance could be regarded as not rapidly degradable when the probability is less than 0,5 estimated by the linear or non-linear methods in accordance with the Biodegradation Probability Program (BIOWIN version 3.67, Syracuse Research Corporation) and the publications of the OECD, 1994, Pedersen *et al.*, 1995 and Langenberg *et al.*, 1996. Other QSAR methods may be when degradation data for structurally analogue compounds are available, and provided that such judgement is conducted with great care. In general, a QSAR prediction that a substance is not rapidly degradable is considered a better documentation for a classification than application of a default classification, when no useful degradation data are available.

#### **G.4.2.4.12 Volatilization**

Chemical substances could be removed from some aquatic environments by volatilization. The Henry's Law constant (H) determines the potential for a substance to volatilize. Volatilization from the aquatic environment is highly dependent on the environmental conditions of the water in question, such as depth, the gas exchange coefficients (depending on wind speed and water flow) and stratification. Because volatilization only represents removal of a chemical from the water

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phase, the Henry's Law constant cannot be used for assessment of degradation in relation to aquatic hazard classification. Substances that are gases at ambient temperature might, however, be considered further in this regard (also see Pedersen *et al.*, 1995).

### **G.4.2.5 No degradation data available**

When no useful data on degradability are available, either experimentally determined or estimated, the substance should be regarded as not rapidly degradable.

## **G.4.3 General interpretation problems**

### **G.4.3.1 Complex substances**

A complex substance is a multi-component substance and is typically of natural origin. Although single substances are used for classification as hazardous to the environment, complex substances occasionally need to be considered, for example, chemicals produced or extracted from mineral oil or plant material. Such complex substances are defined as a homologous series of substances within a certain range of carbon chain length or degree of substitution (or both) and are considered as single substances in a regulatory context. When this is the case, no major difference in degradability is foreseen and the degree of degradability could be established from tests of the complex chemical. However, a borderline degradation is the exception because some of the individual substances might be rapidly degradable and others might not be rapidly degradable. In such a case a more detailed assessment of the degradability of the individual components in the complex substance is required. When not-rapidly-degradable components constitute a significant part of the complex substance (more than 20 %, or for a hazardous component, an even lower content), the substance should be regarded as not rapidly degradable.

### **G.4.3.2 Availability of the substance**

**G.4.3.2.1** Degradation of organic substances in the environment takes place mostly in the aquatic compartments or in aquatic phases in soil or sediment. Hydrolysis requires the presence of water and the activity of micro-organisms depends on the presence of water. Moreover, biodegradation requires that micro-organisms are directly in contact with the substance. Dissolution of the substance in the water phase that surrounds the micro-organisms is therefore the most direct way for contact between the bacteria and fungi and the substrate.

**G.4.3.2.2** The present standard methods for investigating degradability of chemical substances are developed for readily soluble test compounds and many organic substances are only slightly soluble in water. The standard tests require 2 mg/L to 100 mg/L of the test substance and thus sufficient availability might not be reached for substances with low water solubility. Tests with continuous mixing and/or an increased exposure time, or tests with a special design where concentrations of test substance is lower than the water solubility, might be available on slightly soluble compounds.

### **G.4.3.3 Test duration less than 28 d**

**G.4.3.3.1** A degradation test could be terminated before the 28 d period specified in a standard methods if a degradation greater than, or equal to the pass level obtained. When a lower degradation level is reached, the results should be interpreted carefully as the duration of the test might have been too short for the chemical structure to fully biodegrade. If substantial degradation occurs within a short time period, the situation could be compared with the criterion  $BOD_5/COD \geq 0,5$ . Alternatively, the degradation requirements within the 10 d time window (see G.4.2.2.3) could be taken into account. Under these circumstances, a substance is considered readily degradable (and hence rapidly degradable), if the ultimate

- a) biodegradability exceeds 50 % within 5 d, or
- b) the degradation rate constant during this period is greater than  $0,1/d$  corresponding to a half-life of 7 d.

**G.4.3.3.2** The criteria given in G.4.3.3.1(a) and (b) ensure that a substance has been mineralised rapidly although the test was ended before 28 d and before the pass level was attained. Test data that do not comply with the prescribed pass levels should be interpreted with great caution. It is mandatory to consider whether biodegradability below the pass level was due to a partial degradation of the substance or due to the substance not completely mineralised. If partial degradation is the probable explanation for the observed biodegradability, the substance should be considered not readily biodegradable.

#### **G.4.3.4 Primary biodegradation**

In some tests, disappearance of the parent compound (primary degradation) is determined by the degradation in accordance with specific or group-specific chemical analyses of the test substance. Data on primary biodegradability can be used for demonstrating rapid degradability only when it can be satisfactorily demonstrated that the degradation products formed do not fulfil the criteria for classification as hazardous to the aquatic environment.

#### **G.4.3.5 Conflicting results from screening tests**

**G.4.3.5.1** More than one set of degradation data available for the same substance introduces the possibility of conflicting results. In general, conflicting results for a substance that has been tested several times with an appropriate biodegradability test could be interpreted by a “weight of evidence approach”. This implies that if both positive (higher degradation than the pass level) and negative results have been obtained for a substance in ready biodegradability tests, then the data of the highest quality and the best documentation should be used for determining the ready biodegradability of the substance. However, positive results in ready biodegradability tests could be considered valid, irrespective of negative results, when the scientific quality is good and the test conditions are well documented, that is, the guideline criteria are fulfilled, including the use of non-pre-exposed (non-adapted) inoculum. None of the various screening tests are suitable for the testing of all types of substances. Results obtained by a test procedure that is not suitable for the specific substance should be evaluated carefully before a decision on the use of such a test is taken.

**G.4.3.5.2** Factors that should be taken into account in case of conflicting biodegradability data from screening tests are:

- a) inoculum;
- b) toxicity of test substance;
- c) test conditions;
- d) solubility of the test substance; and
- e) volatilisation of the test substance.

**G.4.3.5.3** The suitability of the inoculum for the degradability the test depends on the presence and the amount of competent degraders. An inoculum obtained from an environment that has previously been exposed to the test substance might be adapted as evidenced by a degradation capacity, greater than that of an inoculum from a non-exposed environment. As far as possible the inoculum should be sampled from an unexposed environment. However, this might be difficult, if not impossible, for substances that are used ubiquitously in high volumes and released widespread or

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more or less continuously. When conflicting results are obtained, the origin of the inoculum should be checked in order to clarify whether or not differences in the adaptation of the microbial community might be the reason.

**G.4.3.5.4** Many substances are toxic or inhibitory to the inoculum where high concentrations (100 mg/L) are prescribed in ready biodegradability tests, especially in OECD Test 301C and OECD Test 301F. The lowest test substance concentrations (2 mg/L to 10 mg/L) are prescribed in OECD Test 301D. The possibility of toxic effects could be evaluated including a toxicity control in the ready biodegradability test or by comparing the test concentration with toxicity test data on micro-organisms, for example the respiration inhibition test (OECD Test 209), the nitrification inhibition test (ISO 9509) or, if other microbial toxicity tests are not available, the bioluminescence inhibition test (ISO 11348). Conflicting results might be caused by toxicity of the test substance. The greatest degradation measured in screening tests should be used as a basis for classification if the substance is not inhibitory at environmentally realistic concentrations. Consideration of simulation test data, if available, is especially important, because a low non-inhibitory concentration of the substance might have been employed, thus giving a more reliable indication of the biodegradation half-life of the substance under environmentally realistic conditions.

**G.4.3.5.5** A solubility of the test substance lower than the concentrations employed in a test is a limiting factor for the actual degradation measured. In such a case, results from tests employing the lowest concentrations of test substance should prevail (see OECD Test 301D). In general, the DOC Die-Away test (OECD Test 301A) and the Modified OECD Screening test (OECD Test 301E) are not suitable for testing the biodegradability of poorly soluble substances (see OECD Test 301).

**G.4.3.5.6** Closed system tests (see OECD Test 301D, OECD Test 301C and OECD Test 301F) should be used for volatile substances. Results from other tests should be evaluated carefully and only considered if it can be demonstrated, for example, by mass balance estimates that the removal of the test substance is not a result of volatilisation.

### **G.4.3.6 Variation in simulation test data**

Simulation test data for certain high priority chemicals provide a range of half-lives in environmental media such as soil, sediment and/or surface water. The observed differences in half-lives from simulation tests performed on the same substance reflect differences in test conditions, all of which might be environmentally relevant. A suitable half-life on the higher end of the observed range of half-lives from such investigations should be selected for classification by employing a weight of evidence approach and taking the realism and relevance of the employed tests into account in relation to environmental conditions. In general, simulation test data of surface water are preferred to aquatic sediment or soil simulation test data for the evaluation of rapid degradability in the aquatic environment.

## **G.4.4 Decision scheme**

**G.4.4.1** The decision scheme given in G.4.4.2 as general guidance to facilitate decisions in on rapid degradability in the aquatic environment and classification of chemicals hazardous to the aquatic environment.

**G.4.4.2** A substance is not rapidly degradable unless at least one of the following requirements is fulfilled and the substance is:

- a) readily biodegradable in a 28 d test for ready biodegradability. A pass level of 70 % DOC removal or a 60 % theoretical oxygen demand has been achieved within 10 d from the onset of biodegradation when evaluated in accordance with available test data. If this is not possible, the pass level should be evaluated within a 14 d time window if possible, or after the end of the test;  
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- b) ultimately degraded in a surface water simulation test (see G.4.2.4.2) with a half-life of less than 16 d (corresponding to a degradation greater than 70 % within 28 d; or
- c) primarily degraded (biotically or abiotically) in the aquatic environment with a half-life less than 16 d (corresponding to a degradation greater than 70 % within 28 d) and the degradation products do not fulfil the criteria for classification as hazardous to the aquatic environment.

**G.4.4.3** When the data given in G.4.4.1 are not available, a substance is rapid degraded if:

- a) it is ultimately degraded in an aquatic sediment or soil simulation test with a half-life of less than 16 d (corresponding to a degradation greater than 70 % within 28 d; or
- b) the ratio of BOD<sub>5</sub>/COD is greater than, or equal to, 0,5 in cases where only BOD<sub>5</sub> and COD data are available. The same criterion applies to ready biodegradability tests of a shorter duration than 28 d and a half-life of less than 7 d.

**G.4.4.4** If none of the data given in G.4.4.2 and G.4.4.3 are available, and no other data on degradability are available, a substance is considered as not rapidly degradable. Such a substance should comply with at least one of the following criteria:

- a) not inherently degradable in an inherent biodegradability test; or
- b) slowly biodegradable by scientifically valid QSARs, for example the Biodegradation Probability Program and the score for rapid degradation (linear or non-linear model) is less than 0,5; or
- c) not rapidly degradable based on indirect evidence, for example knowledge from structurally similar substances.

## **G.5 Bioaccumulation**

### **G.5.1 Introduction**

**G.5.1.1** Bioaccumulation is an important intrinsic property of chemical substances that determines the potential environmental hazard. Bioaccumulation of a substance into an organism is not a hazard in itself. However, bioconcentration (see 3.1.10) and bioaccumulation (see 3.1.8) result in a body burden that might lead to toxic effects. For most organic chemicals uptake from water is believed to be the predominant route of bioconcentration. Only for very hydrophobic substances does uptake from food become important. The harmonized classification criteria use the bioconcentration factor (BCF) (see 3.1.11) (or the octanol/water partition coefficient) as the measure of the potential for bioaccumulation. For the purposes of these guidelines only bioconcentration is taken into account and not the uptake via food or other routes.

**G.5.1.2** The degree of bioconcentration depends on factors such as the degree of bioavailability (see 3.1.9), the physiology of the test organism, maintenance of constant exposure concentration, exposure duration, metabolism inside the body of the target organism and excretion from the body. The interpretation of the bioconcentration potential in a chemical classification context requires an evaluation of the intrinsic properties of the substance, as well as the experimental conditions under which the BCF has been determined.

**G.5.1.3** The bioconcentration properties of a substance could be available from standardized test results or could be estimated from the structure of the molecule. The interpretation of bioconcentration data for classification purposes requires detailed evaluation of test data.

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### **G.5.2 Interpretation of bioconcentration data**

**G.5.2.1** The environmental hazard classification of a chemical substance is normally based on existing data on its environmental properties. Test data are only seldom produced with the main purpose of facilitating a classification. Often a diverse range of test data is available that does not necessarily match the classification criteria and thus guidance is needed on interpretation of existing test data in the context of hazard classification.

**G.5.2.2** The bioconcentration of an organic substance could be experimentally determined and the BCF measured and/or estimated from the uptake rate constant ( $k_1$ ) and the elimination rate constant ( $k_2$ ) (see OECD Test 305). In general, the potential of an organic substance to bioconcentrate is primarily related to the lipophilic properties of the substance. The n-octanol-water coefficient ( $K_{ow}$ ) correlates with the BCF for lipophilic non-ionic organic substances undergoing minimal metabolism or bio-transformation within the organism. Therefore,  $K_{ow}$  is often used for the estimation of the bioconcentration of organic substances based on the empirical relationship between  $\log$  BCF and  $\log K_{ow}$ . For most organic substances, estimation methods are available for calculation of  $K_{ow}$ . Data on the bioconcentration properties of a substance could thus be obtained as follows:

- a) experimentally determined;
- b) estimated from experimentally determined  $K_{ow}$ ; or
- c) estimated from  $K_{ow}$  values derived by use of QSARs.

#### **G.5.2.3 Bioconcentration factor (BCF)**

##### **G.5.2.3.1 General**

**G.5.2.3.1.1** The BCF (see 3.1.11) could be determined experimentally under steady-state conditions on the basis of measured concentrations. Alternatively, it could be calculated as the ratio between the first-order uptake and elimination rate constants, a method that does not require equilibrium conditions (see also G.5.2.3.2).

**G.5.2.3.1.2** Different test guidelines for the experimental determination of bio concentration in fish have been documented and adopted with OECD 305 as the one most generally applied.

**G.5.2.3.1.3** Experimentally derived BCF values of high quality should be used for classification purposes and override surrogate data, for example,  $K_{ow}$ .

**G.5.2.3.1.4** High quality data are attained if the validity criteria for the test method applied are fulfilled and described, for example:

- a) the analytical method used to quantify the chemical and its toxic metabolites in the water and fish tissue;
- b) maintenance of constant exposure concentration;
- c) oxygen and temperature variations,
- d) documentation that steady-state conditions have been reached; and
- e) GLP has been followed.



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**G.5.2.3.1.5** BCF values of low or uncertain quality give false and too low BCF values, for example the application of measured concentrations of the test substance in fish and water, but measured after a too short exposure period in which steady-state conditions have not been reached (see OECD Test 306 regarding the estimation of the time to equilibrium). Therefore, such data should be carefully evaluated and  $K_{ow}$  data should rather be used instead.

**G.5.2.3.1.6** If no BCF value for fish species is available, high-quality data on the BCF value for other species may be used, for example, on blue mussel, oyster and scallop (see ASTM E 1022-94). However, reported BCFs for microalgae should be used with caution.

**G.5.2.3.1.7** For highly lipophilic substances, for example,  $\log K_{ow}$  above 6, experimentally derived BCF values tend to decrease with increasing  $\log K_{ow}$ . Conceptual explanations of this non-linearity are reduced membrane permeation kinetics or reduced biotic lipid solubility for large molecules. A low bioavailability and a low uptake of highly lipophilic substances in the organism thus occur.

Other factors comprise experimental artefacts, such as equilibrium not being reached, reduced bioavailability due to sorption to organic matter in the aqueous phase, and analytical errors. Special care should thus be taken when evaluating experimental data on BCF for highly lipophilic substances as such data will have a much higher level of uncertainty than BCF values determined for less lipophilic substances.

### **G.5.2.3.2 BCF in different test species**

**G.5.2.3.2.1** BCF values used for classification are based on whole body measurements and are derived by means of OECD Test 305 or any other internationally recognized test method that uses small fish. Due to the higher gill surface-to-weight ratio for smaller organisms than for larger organisms, steady-state conditions would be reached sooner in smaller organisms than in larger ones. The size of the organisms (fish) used in bioconcentration studies is thus of considerable importance in relation to the time used in the uptake phase, when the reported BCF value is based solely on the measured concentrations in fish and water at steady-state. Thus, if large fish, e.g. adult salmon, have been used in bioconcentration studies, it should be evaluated whether the uptake period was sufficiently long for steady state to be reached or to allow for a kinetic uptake rate constant to be determined precisely.

**G.5.2.3.2.2** When existing data is used for classification, BCF values could be derived from several different fish or other aquatic species, for example clams, and for different organs in the fish. A close relationship exists between the lipid content of a fish or an aquatic organism and the observed BCF value. Therefore, when comparing BCF values across different fish species or when converting BCF values for specific organs to whole body BCFs, the common approach would be to express the BCF values on common lipid content. For example, if whole body BCF values or BCF values for specific organs are found in literature, the first step would be to calculate the BCF on a percentage lipid basis using the relative content of fat in the fish or organ. Secondly, the BCF for the whole body for a typical aquatic organism (small fish) should be calculated assuming a common default lipid content. A default value of 5 % is most commonly used (Pedersen *et al.*, 1995) as this represents the average lipid content of the small fish in accordance with the OECD Test 305.

**G.5.2.3.2.3** Generally, the highest valid BCF value expressed on this common lipid basis is used to determine the wet-mass based BCF-value in relation to the cut-off value for a BCF value of 500 (see table 56).

### **G.5.2.3.3 Use of radiolabelled substances**

**G.5.2.3.3.1** The use of radiolabelled test substances could facilitate the analysis of water and fish samples. However, unless combined with a specific analytical method, the radioactivity measurements potentially reflect the presence of the parent substance and possible metabolite(s), and possible metabolised carbon that have been incorporated in the fish tissue in organic molecules. As a result of this BCF values determined from data obtained by means of radiolabelled substances are normally overestimated (see also G.5.2.3.3.2).

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**G.5.2.3.3.2** When using radiolabelled substances, the relevant radioactive isotope is usually placed in the stable part of the molecule. Because of this, the measured BCF value includes the BCF of the metabolites. In some cases the metabolite is the most toxic substance and has the highest bioconcentration potential. Measurements of the parent substance as well as the metabolites are thus important for the interpretation of the aquatic hazard (including the bioconcentration potential) of such substances.

**G.5.2.3.3.3** High concentrations of radioactivity are often found in the gall bladder of fish where substances have been radiolabelled. This is caused by bio-transformation in the liver and subsequently by excretion of metabolites in the gall bladder, especially when fish do not feed. The feeding regime thus has a pronounced effect on the measured BCF and it is essential that it be evaluated together with the other parameters.

**G.5.2.3.3.4** If the BCF in terms of radiolabelled residues is equal to, or greater than, 1000, identification and quantification of degradation products, representing at least 10 % of the total residues in fish tissues at steady-state, radiolabelling is strongly recommended for pesticides (see OECD Test 305). If no identification and quantification of metabolites are available, the assessment of bioconcentration should be based on the measured radiolabelled BCF value. If, for highly bioaccumulative substances ( $BCF \geq 500$ ), only BCFs based on the parent compound and on radiolabelled measurements are available, the latter should thus be used in relation to classification.

### **G.5.2.4 Octanol-water-partitioning coefficient ( $K_{ow}$ )**

#### **G.5.2.4.1 General**

**G.5.2.4.1.1** Experimentally derived high-quality  $K_{ow}$  values or values evaluated in reviews and assigned as the “recommended values”, are preferred for organic substances over other determinations of  $K_{ow}$ . When no experimental data of high quality are available, validated QSARs for  $\log K_{ow}$  should be used for classification. Such validated QSARs may be used without modification to the agreed criteria if they are restricted to chemicals for which their applicability is well characterized. A QSAR estimated value of  $K_{ow}$  or an estimate based on individual n-octanol and water solubility should be provided instead of an analytical determination of  $K_{ow}$  for

- a) strong acids and bases,
- b) substances that react with the eluant, or
- c) surface-active substances.

**G.5.2.4.1.2** Measurements should be taken on the ionisable substances in their non-ionised form (free acid or free base) only by means of an appropriate buffer with pH below the pK for free acid or above the pK for free base.

#### **G.5.2.4.2 Experimental determination of $K_{ow}$**

**G.5.2.4.2.1** Different techniques, for example, the Shake Flask and high-performance liquid chromatography (HPLC) methods are described in OECD Test 107 and OECD Test 117 respectively for the experimental determination of  $K_{ow}$  values).

**G.5.2.4.2.2** The shake-flask method applies only to pure substances soluble in water and n-octanol and when the  $\log K_{ow}$  value falls within the range  $-2$  to  $4$ . Data obtained by means of a slow-stirring method are generally more reliable for highly lipophilic substances that slowly dissolve in water. Experimental difficulties associated with the formation of microdroplets during the shake-flask experiment could, to some degree, be overcome by a slow stirring method where water, n-octanol, and the test compound are equilibrated in a gently stirred reactor. The slow-stirring method gives a precise and accurate determination of the  $K_{ow}$  for compounds with a  $\log K_{ow}$  of up to  $8,2$ .

**G.5.2.4.2.3** The HPLC method is applicable for  $\log K_{ow}$  in the interval nil to 6. However, it is less sensitive to the presence of impurities in the test compound compared to the shake-flask method.

**G.5.2.4.2.4** Another technique that could be considered for the determination of  $\log K_{ow}$  is the generator column method (USEPA 1985).

**G.5.2.4.2.5** Experimental determination of the  $K_{ow}$  is not always possible, for example, for highly water-soluble substances, very lipophilic substances and surfactants. In such cases QSAR-derived  $K_{ow}$  may be used.

#### **G.5.2.4.3 Use of QSARs for the determination of $\log K_{ow}$**

Numerous QSARs have been, and continue to be, developed for the estimation of  $K_{ow}$ . Four commercially available PC programmes (CLOGP, LOGKOW (KOWWIN), AUTOLOGP, SPARC) are frequently used for risk assessment if no experimentally derived data are available. CLOGP, LOGKOW and AUTOLOGP are based on the addition of group contributions, while SPARC is based on a more fundamental chemical structure algorithm. SPARC is the only program suitable to be used for inorganic or organometallic compounds. Special methods are needed for the estimation of  $\log K_{ow}$  for surface-active compounds, chelating compounds and mixtures. CLOGP is recommended in the US EPA/EC joint project on validation of QSAR estimation methods (US EPA/EC 1993). Pedersen *et al.* (1995) recommended the CLOGP and the LOGKOW programmes for classification purposes because of their reliability, commercial availability, and convenience of use. The estimation methods recommended for classification purposes are given in table G.2.

**Table G.2 — Recommended QSARs for the estimation of  $K_{ow}$**

1	2	3
Model	$\log K_{ow}$ range	Substance utility
CLOGP	$0 < \log K_{ow} < 9^a$	Calculation of $\log K_{ow}$ for organic compounds containing C, H, N, O, halogens, P, and/or S.
LOGKOW (KOWWIN)	$-4 < \log K_{ow} < 8^b$	Calculation of $\log K_{ow}$ for organic compounds containing C, H, N, O, halogens, Si, P, Se, Li, Na, K, and/or Hg. Additionally, indication of the presence of some surfactants, for example, alcohol ethoxylates, dyestuffs and dissociated substances.
AUTOLOGP	$\log K_{ow} > 5$	Calculation of $\log K_{ow}$ for organic compounds containing C, H, N, O, halogens, P and S.
SPARC	Provides improved results over KOWWIN and CLOGP for compounds with $\log K_{ow} > 5$	A mechanistic model based on chemical thermodynamic principles rather than a deterministic model rooted in knowledge obtained from observational data. Therefore, SPARC differs from models that use QSARs (i.e. KOWWIN, CLOGP, AUTOLOGP) in that no measured $\log K_{ow}$ data are needed for a training set of chemicals. SPARC is the only program suitable to be used for inorganic or organometallic compounds.
<p><sup>a</sup> Experimentally determined <math>\log K_{ow}</math> values compared with estimated values showed that the program accurately predicts the <math>\log K_{ow}</math> for a great number of organic chemicals in the <math>\log K_{ow}</math> range of less than naught to more than nine (<math>n = 501</math>, <math>r^2 = 0,967</math>).</p> <p><sup>b</sup> Based on a scatter plot of estimated versus experimental <math>\log K_{ow}</math> values (Syracuse Research Corporation, 1999), where 13058 compounds have been tested. LOGKOW is evaluated as being valid for compounds with a <math>\log K_{ow}</math> in the interval <math>-4</math> to <math>8</math>.</p>		

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### **G.5.3 Chemical classes that need special attention with respect to BCF and $K_{ow}$ values**

#### **G.5.3.1 General**

Certain physico-chemical properties of a substance might complicate the determination of BCF or its measurement. Examples of such substances are those that do not bioconcentrate in a manner consistent with their other physico-chemical properties, for example steric hindrance and surface activity that makes both the measurement and use of  $\log K_{ow}$  inappropriate.

#### **G.5.3.2 Difficult substances**

**G.5.3.2.1** Difficult to test substances are be poorly soluble, volatile, or subject to rapid degradation due to such processes as photo transformation, hydrolysis, oxidation, or biotic degradation (see also G.3.5).

**G.5.3.2.2** For an organic compound to bioconcentrate, the substance needs to be soluble in lipids, present in the water, and available for transfer across the fish gills. Properties that alter the availability thus change the actual bioconcentration of a substance when compared with that of the prediction. For example, a readily biodegradable substance might only be present in the aquatic compartment for short periods of time. Similarly, volatility and hydrolysis reduce the concentration and the time during which a substance is available for bioconcentration. Adsorption, either to particulate matter or to surfaces is an important parameter that could reduce the actual exposure concentration of a substance. A number of substances are rapidly transformed in the organism, thus leading to a lower BCF value than expected. Substances that form micelles or aggregates might bioconcentrate to a lower extent than would be predicted from simple physico-chemical properties. This is also the case for hydrophobic substances that are contained in micelles formed as a consequence of the use of dispersants. Therefore, the use of dispersants in bioaccumulation tests is discouraged.

**G.5.3.2.3** Measured BCF and  $K_{ow}$  values, based on the parent substance, are a prerequisite for the determination of the bioconcentration potential for difficult to test substances. Furthermore, proper documentation of the test concentration is a prerequisite for the validation of the given BCF value.

#### **G.5.3.3 Poorly soluble and complex substances**

**G.5.3.3.1** Special attention should be paid to poorly soluble substances. The solubility of these substances is often recorded as less than the detection limit and this creates problems with the interpretation of the bioconcentration potential. Therefore, the bioconcentration potential for such substances should be based on the experimental determination of  $\log K_{ow}$  or the QSAR estimations of  $\log K_{ow}$ .

**G.5.3.3.2** When a multi-component substance is not fully soluble in water, it is important to

- a) identify the components of the mixture as far as practically possible, and
- b) examine the possibility of determining its bioaccumulation potential by means of available information on its components.

**G.5.3.3.3** A complex substance should be regarded as bioaccumulating when the bioaccumulating components constitute a significant part of the complex substance, for example, more than 20 % or lower for more hazardous components.

#### **G.5.3.4 High molecular mass substances**

Above certain molecular dimensions, the potential of a substance to bioconcentrate decreases. This is possibly due to steric hindrance of the passage of the substance through gill membranes. A cut-off limit of 700 for the molecular mass has been proposed by the European Commission in 1996 but was subject to criticism and an alternative cut-off limit of 1000 has been proposed in relation to exclusion of consideration of substances with possible indirect aquatic effects. In general, bioconcentration of possible metabolites or environmental degradation products of large molecules should be considered. Data on bioconcentration of molecules with a high molecular mass should therefore be carefully evaluated and only used if such data are considered to be fully valid in respect to both the parent compound, its possible metabolites and environmental degradation products.

#### **G.5.3.5 Surface-active agents**

##### **G.5.3.5.1 General**

Surface active agents (surfactants) consist of a lipophilic (most often an alkyl chain) and a hydrophilic part (the polar headgroup). According to the charge of the headgroup, surfactants are subdivided into classes of anionic, cationic, non-ionic, or amphoteric surfactants. Due to the variety of different headgroups, surfactants are a structurally diverse class of compounds that is defined by surface activity rather than by chemical structure. The bioaccumulation potential of surfactants should thus be considered in relation to the different subclasses (anionic, cationic, non-ionic, or amphoteric) instead of to the group as a whole. Bioavailability is difficult to ascertain for surface-active agents that form emulsions. Furthermore, micelle formation could result in a change of the bioavailable fraction even when the solutions are apparently formed, thus giving problems with the interpretation of the bioaccumulation potential.

##### **G.5.3.5.2 Experimentally derived BCF values**

Experimentally derived BCF values on surfactants show that the BCF might increase with increasing alkyl chain length and be dependant of the site of attachment of the head group, and other structural features.

##### **G.5.3.5.3 Octanol-water-partition coefficient ( $K_{ow}$ )**

The octanol-water partition coefficient for surfactants cannot be determined by means of the shake-flask or slow-stirring method (see G.5.2.4.2.2) because emulsion formation. In addition, the surfactant molecules exist in the water phase almost exclusively as ions, whereas they have to pair with a counter-ion in order to be dissolved in n-octanol. Therefore, the experimental determination of  $K_{ow}$  does not characterize the partition of ionic surfactants. On the other hand the bioconcentration of anionic and non-ionic surfactants increases with increasing lipophilicity. An estimated  $\log K_{ow}$  value determined by means of the LOGKOW programme could represent the bioaccumulation potential and for other surfactants some "correction" to the estimated  $\log K_{ow}$  value need to be made as the quality of the relationship between  $\log K_{ow}$  estimates and bioconcentration depends on the class and specific type of surfactants involved. Therefore, the classification of the bioconcentration potential based on  $\log K_{ow}$  values should be used with caution.

#### **G.5.4 Conflicting data and lack of data**

##### **G.5.4.1 Conflicting BCF data**

**G.5.4.1.1** Where multiple BCF data are available for the same substance, the possibility of conflicting results might arise. In general, conflicting results for a substance that has been subjected several times to an appropriate test for bioconcentration should be interpreted by a "weight of evidence approach". This implies that if experimental determined BCF data of both more than

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500 and less than 500 have been obtained for a substance, the data of the highest quality and with the best documentation should be used for determining the bioconcentration potential of the substance. If differences still exist, for example high-quality BCF values for different fish species are available, the highest valid value should be used as the basis for classification.

**G.5.4.1.2** When larger data sets (4 or more values) are available for the same species and life stage, the geometric mean of the BCF values may be used as the representative BCF value for that species.

### **G.5.4.2 Conflicting log $K_{ow}$ data**

Where multiple log  $K_{ow}$  data are available for the same substance, the possibility of conflicting results might arise. Data of the highest quality and with the best documentation should be used for determination of the bioconcentration potential of a substance where log  $K_{ow}$  values higher than 4 and lower than 4 have been obtained for the substance. If differences still exist, the highest valid value should take precedence and a QSAR estimated log  $K_{ow}$  could be used.

### **G.5.4.3 Expert judgement**

If no experimental BCF, log  $K_{ow}$  data and predicted log  $K_{ow}$  data are available, the potential for bioconcentration in the aquatic environment should be assessed by expert judgement. This could be based on a comparison of the structure of the molecule with the structure of other substances for which experimental bioconcentration or log  $K_{ow}$  data or predicted  $K_{ow}$  are available.

## **G.5.5 Decision scheme**

**G.5.5.1** A decision scheme has been developed to facilitate decisions as to whether or not a substance has the potential for bioconcentration in aquatic species.

**G.5.5.2** Experimentally derived BCF values of high quality should be used for classification purposes. If data on log  $K_{ow}$  are available, BCF values of low or uncertain quality should not be used for classification purposes as they might give a false and too low BCF value, e.g. due to a short exposure period in which steady-state conditions have not been reached. If no BCF is available for fish species, high quality data on the BCF for other species, for example, mussels may be used.

**G.5.5.3** Experimentally derived high quality  $K_{ow}$  values, or values that were evaluated in reviews and assigned as the "recommended values", should be used for organic substances. If no experimental data of high quality are available, validated QSARs for log  $K_{ow}$  may be used. Such validated QSARs could be used without modification in relation to the classification criteria, provided that it is restricted to chemicals for which their applicability is well characterized. For substances like strong acids and bases, metal complexes, and surface-active substances, a QSAR estimated value of  $K_{ow}$  or an estimate based on individual n-octanol and water solubility should be provided instead of an analytical determination of  $K_{ow}$ .

**G.5.5.4** If data are available but not validated, expert judgement should be used.

**G.5.5.5** A decision on the potential for bioconcentration of a substance in aquatic organisms could be reached by means of the following scheme:

**Valid/high quality experimentally determined BCF value → YES**

→BCF  $\geq$  500: *The substance has a potential for bioconcentration*

→BCF < 500: *The substance does not have a potential for bioconcentration.*



**Valid/high quality experimentally determined BCF value → NO**

- Valid/high quality experimentally determined  $\log K_{ow}$  value → YES:
- $\log K_{ow} \geq 4$ : *The substance has a potential for bioconcentration*
- $\log K_{ow} < 4$ : *The substance does not have a potential for bioconcentration.*

**Valid/high quality experimentally determined BCF value → NO**

- Valid/high quality experimentally determined  $\log K_{ow}$  value → NO:
- Use of validated QSAR for estimating a  $\log K_{ow}$  value → YES:
- $\log K_{ow} \geq 4$ : *The substance has a potential for bioconcentration*
- $\log K_{ow} < 4$ : *The substance does not have a potential for bioconcentration.*

## **G.6 Classification of metals and metal compounds**

### **G.6.1 Introduction**

**G.6.1.1** The hazards of metal and metal compounds to the aquatic environment are limited to that fraction of the compound dissolved in the water column and that exist as dissolved metal ion ( $M^+$ ) when present as  $M-NO_3$ . The non-metallic ion (for example  $CN^-$ ) of a metal compound might be toxic or organic and could pose bioaccumulation or persistence hazards. The hazards of such a non-metallic ion should also be considered.

**G.6.1.2** The level of the metal ion present in solution after the addition of a metal or its compounds to water is determined by the extent to which it

- a) dissolves, that is, its water solubility, and
- b) reacts with the media to transform to water soluble forms.

**G.6.1.3** The rate and extent at which the “transformation” takes place could vary extensively between different compounds and the metal itself, and is an important factor in determining the appropriate hazard class. Where data on transformation are available, they should be taken into account in determining the classification (see annex H for the protocol for determination of the rate of transformation).

**G.6.1.4** The rate at which a substance dissolves is not considered relevant to the determination of its intrinsic toxicity. However, for metals and many poorly soluble inorganic metal compounds, the difficulties in achieving dissolution through normal solubility techniques are so severe that the processes of solubility and transformation become indistinguishable. The rate and extent of transformation should, however, be considered where a metal and/or its compounds is so poorly soluble that the solubility levels do not exceed the available toxicity limits ( $L(E)C_{50}$ ) when the metal/metal compounds has been subjected to normal dissolution techniques. The transformation is affected by a number of factors such as the properties of the media with respect to pH, water hardness, temperature etc. In addition to these properties, other factors such as the size and specific surface area of the particles that have been tested, the length of time over which exposure to the media takes place and the mass or surface area loading of the substance in the media all play a part in determining the level of dissolved metal ions in water. Transformation data could therefore only be considered as reliable for the purposes of classification if conducted in accordance with the standard protocol in annex H.

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**G.6.1.5** A number of factors have to be taken into account when considering the classification of both readily and poorly soluble metals and metal compounds. For inorganic compounds and metals, the concept of degradability (see 3.1.23 and 11.2.4), has limited, or no meaning, as normal environmental processes might increase or decrease the bioavailability of the toxic species. Likewise, the  $\log K_{ow}$  cannot be taken into account as a measure of the potential to accumulate. However, the concept that a substance, or a toxic metabolite/reaction product might not be rapidly lost from the environment or bioaccumulate (or both), is applicable to metals and metal compounds as they are to organic substances.

**G.6.1.6** Speciation of the soluble form could be affected by pH, water hardness and other variables and yield particular forms of the metal ion that are more or less toxic. In addition, metal ions could be made non-available from the water column by a number of processes, for example, mineralisation and partitioning. Sometimes these processes are sufficiently rapid to be analogous to degradation in assessing chronic classification. However, partitioning of the metal ion from the water column to other environmental media does not necessarily mean that it is no longer bioavailable, nor does it mean that the metal has been made permanently unavailable.

**G.6.1.7** Information pertaining to the extent of the partitioning of a metal ion from the water column, or the extent to which a metal has been or could be converted to a form that is less toxic or non-toxic is frequently not available over a sufficiently wide range of environmentally relevant conditions and thus a number of assumptions need to be made as an aid in classification. These assumptions may be modified if available data show otherwise. In the first instance it should be assumed that the metal ions, once in the water, are not rapidly partitioned from the water column and thus these compounds do not meet the criteria. Underlying this is the assumption that, although speciation could occur, the species remain available under environmentally relevant conditions. This might not always be the case any evidence available that suggests changes to the bioavailability over the course of 28 d should be carefully examined. The bioaccumulation of metals and inorganic metal compounds is a complex process and bioaccumulation data should be used with care. The application of bioaccumulation criteria should be considered on a case-by-case basis taking due account of all the available data.

**G.6.1.8** Another assumption that should be approached with caution is that, in the absence of any solubility data for a particular metal compound, either measured or calculated, the substance would be sufficiently soluble to cause toxicity at the level of the  $L(E)C_{50}$ , and thus be classified in the same way as other soluble salts. However, this is clearly not always the case and it might be wise to generate appropriate solubility data.

**G.6.1.9** Within the context of this standard metals and metal compounds, with the exception of organo-metals, are characterized as follows:

- a) metals in their elemental state ( $M^0$ ) that are insoluble in water but might be transformed to the available form. This means that a metal in the elemental state might react with water or a dilute aqueous electrolyte to form soluble cationic or anionic products and in the process oxidize, or transform, from the neutral or zero oxidation state to a higher one; and
- b) simple metal compounds, such as oxides or sulphides, that already exist in the oxidized state so that further metal oxidation is unlikely to occur when the compound is introduced into an aqueous medium.

**G.6.1.10** While the oxidation state of a metal/metal compound might not change, interaction with the media could yield more soluble forms. A sparingly soluble metal compound could be considered as one for which a solubility product can be calculated and that might yield a small amount of the available form by dissolution. However, it should be recognized that the final solution concentration might be influenced by a number of factors, including the solubility product of some metal compounds precipitated during the transformation/dissolution test, for example, aluminium hydroxide.



## **G.6.2 Application of aquatic toxicity data and solubility data for classification**

### **G.6.2.1 Interpretation of aquatic toxicity data**

Aquatic toxicity studies carried out on a metal /metal compound in accordance with an international recognized protocol would normally be acceptable for the purposes of classification. Generic issues that are common to the assessment of aquatic toxicity data for the purposes of classification are given in G.6.5.

### **G.6.2.2 Metal complexation and speciation**

**G.6.2.2.1** The toxicity of a particular metal in solution depends primarily on (but is not limited to) the level of dissolved free metal ions. Abiotic factors including alkalinity, ionic strength and pH could influence the toxicity of metals in two ways:

- a) chemical speciation of the metal in water (and hence affecting the availability); and
- b) uptake and binding of available metal by biological tissues.

**G.6.2.2.2** Where speciation is important, it might be possible to model the concentrations of the different forms of the metal, including those that are likely to cause toxicity. Methods for quantifying exposure concentrations and distinguish between complexed fractions and uncomplexed fractions of the test substance might not always be available or economic.

**G.6.2.2.3** Complexation of metals to organic and inorganic ligands in test media and natural environments could be estimated from metal speciation models. Speciation models for metals, such as MINTEQA (Brown and Allison, 1987), WHAM (Tipping, 1994) and CHESS (Santore and Driscoll, 1995) including pH, hardness, DOC, and inorganic substances may be used to calculate the uncomplexed and complexed fractions of the metal ions. Alternatively, the Biotic Ligand Model (BLM) allows for the calculation of the concentration of metal ion responsible for the toxic effect at the level of the organism. The BLM model has at present only been validated for a limited number of metals, organisms, and end-points (Santore and Di Toro, 1999). The models and formula used for the characterization of metal complexation in the test media should always be clearly reported, allowing for their translation back to natural environments.

### **G.6.2.3 Interpretation of solubility data**

The validity and applicability of available data on solubility should be assessed with regard to the identification of the hazards of metal compounds. In particular, knowledge of the pH at which the data were generated should be known.

### **G.6.2.4 Assessment of existing data**

Existing data are normally available in one of the following forms:

- a) for some well-studied metals, solubility products and/or solubility data for the various inorganic metal compounds; or
- b) the pH relationship of the solubility is known; or
- c) for many metals or metal compounds, the available information is descriptive only, for example, "poorly soluble". Unfortunately there appears to be very little (consistent) guidance about the solubility ranges for such descriptive terms. Where these are the only information available it is probable that solubility data need to be generated by applying the transformation/dissolution protocol as given in annex H.

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### **G.6.2.5 Screening test for assessing the solubility of metal compounds**

In the absence of solubility data a screening test for the assessment of solubility, based on the high rate of loading for 24 h, could be used for metal compounds (see annex H). The screening test identifies the metal compounds that undergo either dissolution or rapid transformation such that they are indistinguishable from soluble forms and hence could be classified based on the dissolved ion concentration. Where data are available from the screening test, the maximum solubility obtained over the tested pH range should be used. Where data are not available over the full pH range, a check should be made that the maximum solubility has been achieved by reference to suitable thermodynamic speciation models or other suitable methods (see G.6.2.2.3).

### **G.6.2.6 Full test for assessing solubility of metals and metal compounds**

**G.6.2.6.1** The first step in this part of the study is, as with the screening test, an assessment of the pH at which the study should be conducted. Normally, the full test should be carried out at the pH that maximizes the concentration of dissolved metal ions in solution. In such cases, the pH may be chosen by following the same guidance as given for the screening test.

**G.6.2.6.2** Based on the data from the full test, it is possible to generate a concentration of the metal ions in solution after 7 d for each of the three loadings (1 mg/L is regarded as “low”, 10 mg/L as “medium” and 100 mg/L as “high”) used in the test. If the purpose of the test is to assess the long-term hazard of the substance, then the test at the low loading may be extended to 28 d, at an appropriate pH.

### **G.6.2.7 Comparison of aquatic toxicity data and solubility data**

A comparison between the aquatic toxicity data and solubility data determines whether a substances should be classified. If the  $L(E)C_{50}$  is exceeded, irrespective of whether the toxicity and dissolution data are at the same pH and if this is the only data available, the substance should be classified. If other solubility data are available to show that the dissolution concentration would not exceed the  $L(E)C_{50}$  across the entire pH range then the substance should not be classified based on its soluble form. This might involve the use of additional data either from ecotoxicological testing or from applicable bioavailability-effect models.

## **G.6.3 Assessment of environmental transformation**

**G.6.3.1** Environmental transformation of one species of a metal to another species of the same metal does not constitute degradation as applied to organic compounds and might increase or decrease the availability and bioavailability of the toxic species. However, as a result of naturally occurring geochemical processes, metal ions can partition from the water column. Data on water column residence time, the processes involved at the water-sediment interface (i.e. deposition and re-mobilization) are fairly extensive, but have not been integrated into a meaningful database. Nevertheless, by using the principles and assumptions discussed in G.6.1, it might be possible to incorporate this approach into classification.

**G.6.3.2** Assessment of environmental transformation is very difficult and would normally be addressed on a case-by-case approach. However, the following may be taken into account:

- a) speciation changes into non-available forms. However, the potential for the reverse change to occur should also be considered; and
- b) changes to a metal compound which is considerably less soluble than that of the metal compound under consideration (see also G.6.1.4 and G.6.1.5).

## **G.6.4 Bioaccumulation**

**G.6.4.1** Log  $K_{ow}$  is a good predictor of BCF for certain types of organic compounds, for example, non-polar organic substances, but is irrelevant for inorganic substances such as inorganic metal compounds.

**G.6.4.2** The mechanisms for uptake and depuration rates of metals are very complex and variable and at present no general model is available to describe this. Thus, the bioaccumulation of metals should be evaluated on a case-by-case basis using expert judgement.

**G.6.4.3** While BCFs are indicative of the potential for bioaccumulation, a number of complications could be experienced with the interpretation of the measured BCF values for metals and inorganic metal compounds and the following should be taken into consideration:

- a) the relationship between water concentration and BCF is inverse in some aquatic organisms;
- b) bioconcentration data should be used with caution, in particular for metals that are biologically essential;
- c) nutritional requirement of the organisms might be higher than the environmental concentration and this could result in high BCFs and an inverse relationship between BCFs and the concentration of the metal in water;
- d) at low environmental concentrations high BCFs could be expected as a natural consequence of metal uptake to meet nutritional requirements and should be viewed as a normal phenomenon;
- e) measured BCFs might decline as external concentration increases when internal concentration is regulated by the organism;
- f) external concentrations that are so high that they exceed a threshold level or overwhelm the regulatory mechanism, could cause harm to the organism; and
- g) a metal might be essential in a particular organism but might not be essential in other organisms. Therefore, where the metal is not essential or when the bioconcentration of an essential metal is above nutritional levels, special consideration should be given to the potential for bioconcentration and environmental concern.

## **G.6.5 Application of classification criteria to metals and metal compounds**

### **G.6.5.1 Introduction to the classification strategy for metals and metal compounds**

**G.6.5.1.1** There are several stages in the classification scheme where data are required for decision purposes. In the absence of valid data, it is necessary to use available data and expert judgement.

**G.6.5.1.2** In the classification strategy for metals and metal compounds  $L(E)C_{50}$  refers to the data point(s) that should be used to select the classification band for the metal or metal compound.

**G.6.5.1.3** When considering  $L(E)C_{50}$  data for metal compounds, it is important to ensure that the data point to be used as the justification for the classification is expressed in the molecular mass of the metal compound to be classified. Thus, while most metal data are expressed in, for example, mg/L of the metal, this value should be adjusted as follows:

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$$A = B \times \frac{M}{m}$$

where

*A* is the toxicity of the metal compound, expressed in  $L(E)C_{50}$ ;

*B* is the toxicity of the metal, expressed in  $L(E)C_{50}$ ;

*M* is the molecular mass of the metal compound;

*m* is the atomic mass of the metal.

NOTE NOEC data may also need to be adjusted to the corresponding mass of the metal compounds.

### G.6.5.2 Classification strategy for metals

#### G.6.5.2.1 General

**G.6.5.2.1.1** A metal need not be considered in the classification scheme if the  $L(E)C_{50}$  for the relevant metal ions is greater than 100 mg/L.

**G.6.5.2.1.2** Where the  $L(E)C_{50}$  for the metal ions under consideration is less than or equal to 100 mg/L, consideration shall be given to the data available on the rate and extent to which these ions can be generated from the metal. To be valid and useable such data should have been generated in accordance with the transformation/dissolution protocol given in annex H.

**G.6.5.2.1.3** If no clear data of sufficient validity is available to show that the transformation to metal ions will not occur, the “safety net” classification (chronic category 4) should be applied since the known classifiable toxicity of these soluble forms is considered to produce sufficient concern.

**G.6.5.2.1.4** Available data from the dissolution protocol should be used to aid classification in accordance with the rules given in G.6.5.2.2 and G.6.5.2.3.

#### G.6.5.2.2 Seven day transformation test

If the dissolved metal ion concentration exceeds that of the  $L(E)C_{50}$  after a period of 7 d (or earlier), replace the default classification for the metals by the following classification:

- a) **acute category 1**, if the dissolved metal ion concentration at the low loading rate is greater than, or equal to, the  $L(E)C_{50}$ ;
- b) **chronic category 1**, unless there is evidence of both rapid partitioning from the water column and no bioaccumulation;
- c) **acute category 2**, if the dissolved metal ion concentration at the medium loading rate is greater than, or equal to, the  $L(E)C_{50}$ ;
- d) **chronic category 2**, unless there is evidence of both rapid partitioning from the water column and no bioaccumulation;
- e) **acute category 3**, if the dissolved metal ion concentration at the high loading rate is greater than, or equal to, the  $L(E)C_{50}$ ; or
- f) **chronic category 3** unless there is evidence of both rapid partitioning from the water column and no bioaccumulation.

### **G.6.5.2.3 Twenty eight day transformation test**

**G.6.5.2.3.1** If the classification strategy for the 7-d transformation tests (see G.6.5.2.2) results in a classification of chronic category 1, no further assessment is required as the metal is classifiable irrespective of any further information.

**G.6.5.2.3.2** In all other cases, further data generated by means of the transformation test might show that the classification be amended. Thus, classification is not applicable in the case of metal classified as chronic category 2, 3 or 4 where the dissolved metal ion concentration is less than or equal to the long-term NOECs at the low loading rate after a total test period of 28 d.

### **G.6.5.3 Classification strategy for metal compounds**

#### **G.6.5.3.1 General**

A metal compound need not be considered for classification if the  $L(E)C_{50}$  for the relevant metal ions is greater than 100 mg/L.

#### **G.6.5.3.2 Classification on the basis of the soluble ion**

**G.6.5.3.2.1** A metal compound with a water solubility greater or equal to the  $L(E)C_{50}$  of the dissolved metal ion concentration is considered as readily soluble. The water solubility could be determined over a 24 h period by means of the dissolution screening test (see G.6.2.5) or estimated, for example, from the solubility product. The conditions under which solubility is measured could differ significantly from that of the acute toxicity test. Care should thus be exercised for compounds where the solubility is close to the acute toxicity value; in such a case the results obtained by means of the dissolution screening test are preferred.

**G.6.5.3.2.2** Classify readily soluble metal compounds as follows on the basis of the  $L(E)C_{50}$ , corrected molecular mass if applicable, (see G.6.5.1.3):

- a) **acute category 1**, if the  $L(E)C_{50}$  of the dissolved metal ion is less than, or equal to, 1 mg/L;
- b) **chronic category 1**, unless there is evidence of both rapid partitioning from the water column and no bioaccumulation;
- c) **acute category 2**, if the  $L(E)C_{50}$  of the dissolved metal ion is greater than 1 mg/L but less than, or equal to, 10 mg/L;
- d) **chronic category 2**, unless there is evidence of both rapid partitioning from the water column and no bioaccumulation;
- e) **acute category 3**, if the  $L(E)C_{50}$  of the dissolved metal ion is greater than 10 mg/L but less than, or equal to, 100 mg/L; or
- f) **chronic category 3**, unless there is evidence of both rapid partitioning from the water column and no bioaccumulation.

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### **G.6.5.3.3 Classification by default**

#### **G.6.5.3.3.1 General**

**G.6.5.3.3.1.1** The water solubility of a metal compound can be determined over a 24 h period by means of the dissolution screening test (see G.6.2.5 and H.3.9.1) or estimated, for example from the solubility product.

**G.6.5.3.3.1.2** A metal compound is regarded as poorly soluble if the  $L(E)C_{50}$  of the soluble forms of the metal of such a compound is less than or equal to 100 mg/L. The default “safety net” classification (chronic category 4) should be applied for the classification of such a metal compound (see also G.6.5.2.1.3).

#### **G.6.5.3.3.2 Seven day transformation test**

**G.6.5.3.3.2.1** The 7-d transformation test for poorly soluble metal compounds that have been classified by means of the default “safety net” classification could provide additional information that could also be used for classification purposes. Such data should include transformation levels at low, medium and high loading levels.

**G.6.5.3.3.2.2** If the dissolved metal ion concentration exceeds that of the  $L(E)C_{50}$ , after a period of 7 d (or earlier) replace the default classification for the metal compounds by the following classification:

- a) **acute category 1**, if the dissolved metal ion concentration at the low loading rate is greater than or equal to the  $L(E)C_{50}$ ;
- b) **chronic category 1**, unless there is evidence of both rapid partitioning from the water column and no bioaccumulation;
- c) **acute category 2**, if the dissolved metal ion concentration at the medium loading rate is greater than or equal to the  $L(E)C_{50}$ ;
- d) **chronic category 2**, unless there is evidence of both rapid partitioning from the water column and no bioaccumulation;
- e) **acute category 3**, if the dissolved metal ion concentration at the high loading rate is greater than or equal to the  $L(E)C_{50}$ ; or
- f) **chronic category 3**, unless there is evidence of both rapid partitioning from the water column and no bioaccumulation.

#### **G.6.5.3.3.3 Twenty eight day transformation test**

**G.6.5.3.3.3.1** If the classification strategy for the 7-day transformation test (see G.6.5.3.3.2) results in a classification of chronic category 1, no further assessment is required as the metal compound is classifiable irrespective of any further information.

**G.6.5.3.3.3.2** In all other cases, further data generated by means of the transformation test might show that the classification be amended. Thus, classification is not applicable in the case of a poorly soluble metal compound (see G.6.5.3.3.1.2) classified as chronic category 2, 3 or 4 where the dissolved metal ion concentration at the low loading rate is less than or equal to the long-term NOECs after a total test period of 28 d.

## **G.6.6 Particle size and surface area**

**G.6.6.1** Variation in the particle size or surface area of a metal and a metal compound might cause significant changes in the levels of metal ions released in a given time-window. Thus, particle size or surface area is fixed for the purposes of the transformation tests, allowing comparative classifications to be based solely on the loading level. Normally, the smallest particle size in which a metal and a metal compound are marketed is used to determine the extent of transformation. However, there might be cases where data generated for a particular metal powder is not considered suitable for classification of the massive forms. For example, where the tested powder is structurally a different material (different crystallographic structure) and/or it has been produced by a special process and cannot be generated from the massive metal. Classification of the massive form is based on the testing of a more representative particle size or surface area. A metal powder is classified separately based on the data generated on the powder. However, under normal circumstances it is not anticipated that more than two classification proposals would be made for the same metal.

**G.6.6.2** Metals with a particle size smaller than the default diameter value of 1 mm can be tested on a case-by-case basis. For example, where a metal powder is produced by different production techniques or where the powder gives rise to a higher dissolution (or reaction) rate than the massive form and thus leading to a more stringent classification.

**G.6.6.3** The particle sizes tested depend on the substance being assessed and are given in table G.3.

**Table G.3 — Particle size of metals and metal compounds**

1	2	3
Type	Particle size	Comments
Metal compounds	Smallest representative size marketed	Maximum of 1 mm
Metal powders	Smallest representative size marketed	Consider different sources if yielding different crystallographic or morphologic properties
Metals – massive	1 mm	Default value may be altered if sufficient justification

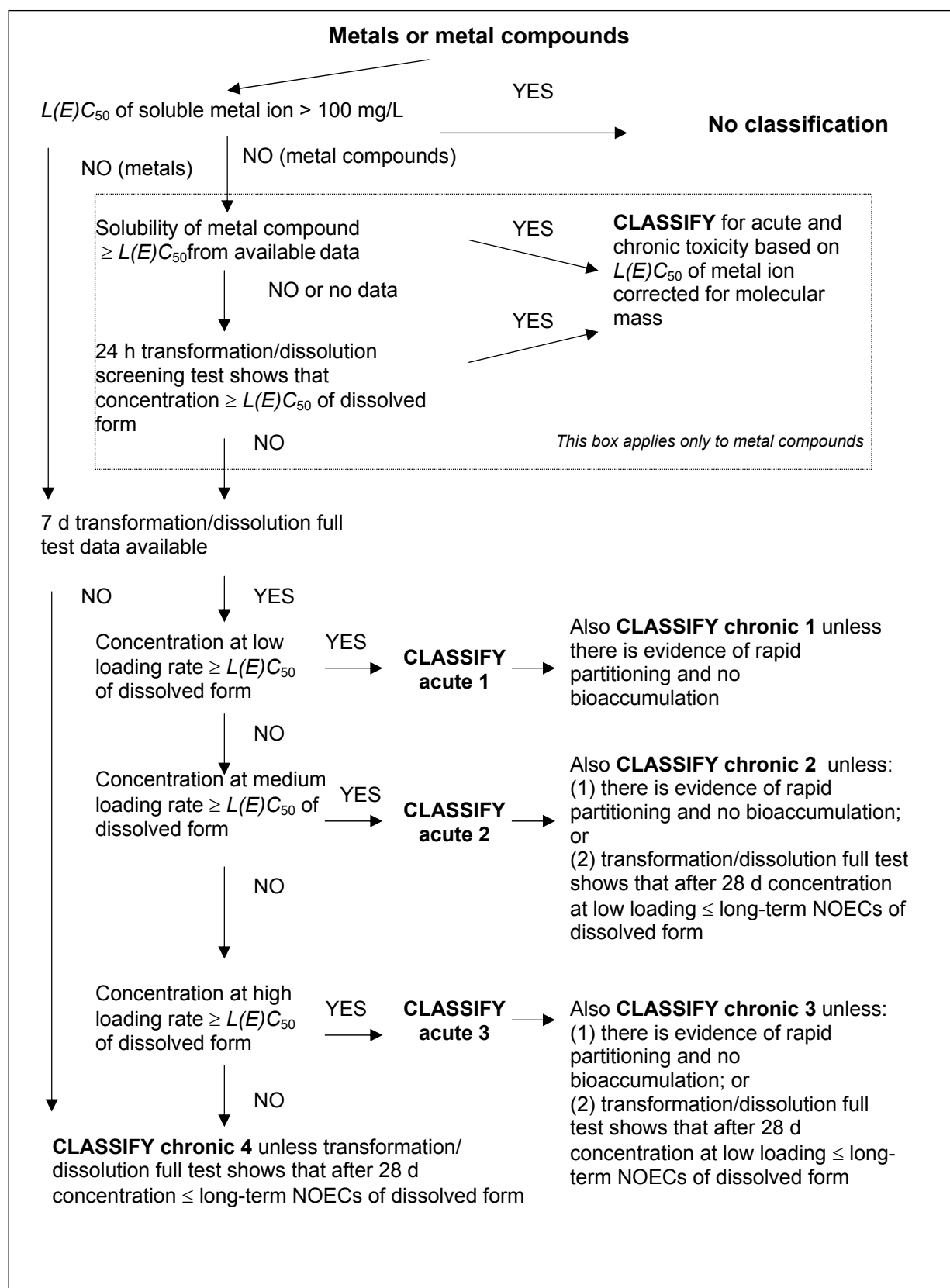
**G.6.6.4** For some forms of metal, it is possible to obtain a correlation between the concentration of the metal ions after a specified time interval as a function of the surface area loadings of the forms tested. In such cases, the level of dissolved metal ion concentration of the metal can be estimated for different particle sizes using the critical surface area approach as proposed by Skeaff *et. al.* (2000). That is, from this correlation and a linkage to the appropriate toxicity data, it may be possible to determine a critical surface area of the substance that delivers the  $L(E)C_{50}$  to the medium and then to convert the critical surface area to the low, medium and high mass loadings used in hazard identification. While this approach is not normally used for classification it could provide useful information for labelling and downstream decisions.



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**Flow chart G.1 — Classification strategy for metals and metal compounds**





# **ANNEX H**

## **TESTING FOR TRANSFORMATION/DISSOLUTION OF METALS AND METAL COMPOUNDS IN AQUEOUS MEDIA**

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## **Annex H**

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### **Testing for transformation/dissolution of metals and metal compounds in aqueous media**

#### **H.1 General**

The tests given in this annex are designed to determine the rate and extent to which metals and sparingly soluble metal compounds produce soluble available ionic and non-metal bearing species in aqueous media under a set of standard laboratory conditions representative of those generally occurring in the environment.

#### **H.2 Screening test for sparingly soluble metal compounds**

Sparingly soluble metal compounds, having the smallest representative particle size on the market, are introduced into the aqueous test medium (see H.3.5.1 and H.3.5.2) at a single loading of 100 mg/L and agitated over a 24 h period and the dissolved metal ion concentration measured (see also H.3.1.2).

#### **H.3 Full test for metals and sparingly soluble metal compounds**

##### **H.3.1 General**

**H.3.1.1** The level of the dissolution/transformation of metals and metal compounds are measured after a certain period of time at different loadings of the aqueous test medium. Normally massive forms or powders (or both) are introduced into the aqueous test medium at loadings of 1 mg/L, 10 mg/L and 100 mg/L. A single loading of 100 mg/L may be used if a significant release of dissolved metal species is not anticipated. Transformation/dissolution is accomplished by standardized agitation, without causing abrasion of the particles. The short-term transformation/dissolution endpoints are based on the dissolved metal ion concentrations obtained after a 7 d test period. The long-term transformation/dissolution endpoint is obtained during a 28 d test period, using a single load of 1 mg/L.

**H.3.1.2** pH has a significant influence on transformation/dissolution of metals and sparingly soluble metal compounds. Therefore, both the screening test and the full test should be carried out at a pH that maximizes the concentration of the dissolved metal ions in solution. With reference to the conditions generally found in the environment, the standard aqueous test medium should be at pH 6 to pH 8,5, except for the 28 d full test where pH 5,5 to pH 6 is applicable in order to take into account possible long-term effects on acidic lakes.

**H.3.1.3** The surface area of the particles in the test specimen has an important influence on the rate and extent of transformation/dissolution. Powders are therefore tested at the smallest representative particle size as placed on the market, while massive metals are tested at a particle size as presented for handling and use. A default particle size of 1 mm is acceptable if information on the particle size of the metal/metal compound, as placed on the market, is not available. For massive metals, this default may only be exceeded when sufficiently justified. The specific surface area should be determined in order to characterize and compare similar specimens.

##### **H.3.2 Applicability**

The test applies to all metals and sparingly soluble inorganic metal compounds. Exceptions, such as certain water reactive metals, should be justified.

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### **H.3.3 Information required on the test substance**

Obtain the following information on the test substance(s) in order to correctly interpret the test results:

- a) substance name, formula and use;
- b) physical-chemical method of preparation;
- c) batch number(s);
- d) purity (%) and specific impurities (% or ppm);
- e) density ( $\text{g/cm}^3$ ) or specific gravity;
- f) surface area ( $\text{m}^2/\text{g}$ ) measured by BET  $\text{N}_2$  adsorption-desorption or equivalent technique;
- g) expiry date;
- h) solubility data and solubility products;
- i) hazard identification and safe handling precautions; and
- j) Safety Data Sheet(s).

### **H.3.4 Apparatus**

**H.3.4.1** 1 L or 3 L glass flask.

**H.3.4.2** Rubber stoppers to fit the flasks.

**H.3.4.3** Laboratory shaker able to be set at 100 r.p.m. or a radial impeller able to be set at 200 rpm and consisting of two fixed polypropylene blades of 40 mm width and 15 mm height on a PVC-coated steel rod 8 mm in diameter and 350 mm long.

**H.3.4.4** Filters, hydrophilic polyethersulfone syringe membrane, diameter 25 mm and pore sizes 0,2  $\mu\text{m}$  and 0,8  $\mu\text{m}$ .

**H.3.4.5** Temperature controlled cabinet or water bath.

**H.3.4.6** Syringe and/or pipette, 20 mL.

**H.3.4.7** pH meter able to measure 0,2 pH units.

**H.3.4.8** Dissolved oxygen meter, with temperature reading capability.

**H.3.4.9** Thermometer or thermocouple.

**H.3.4.10** Atomic absorption spectrometer or inductively coupled plasma spectrometer (ICP).

### H.3.5 Reagents

**H.3.5.1** Standard water with a chemical composition as given in table H.1.

**Table H.1 — Chemical composition of standard aqueous test medium**

1	2	3	4
Chemical composition	pH 6	pH 7	pH 8
Sodium bicarbonate (NaHCO <sub>3</sub> ), mg/L	6,5	12,6	65,7
Potassium chloride (KCl), mg/L	0,58	2,32	5,75
Calcium chloride (CaCl <sub>2</sub> ·H <sub>2</sub> O), mg/L	29,4	117,6	294
Magnesium sulfate (MgSO <sub>4</sub> ·7H <sub>2</sub> O), mg/L	12,3	49,2	123
CO <sub>2</sub> (balance air) in the test vessel, %	–	0,5	0,1

**H.3.5.2** Standard marine test medium and chemical composition as follows:

Sodium fluoride (NaF)	– 3 mg/L
Strontium chloride (SrCl <sub>2</sub> ·6H <sub>2</sub> O)	– 20 mg/L
Boric acid (H <sub>3</sub> BO <sub>3</sub> )	– 30 mg/L
Potassium bromide (KBr)	– 100 mg/L
Potassium chloride (KCl)	– 700 mg/L
Calcium chloride (CaCl <sub>2</sub> ·2H <sub>2</sub> O)	– 1,47 g/L
Sodium sulfate (Na <sub>2</sub> SO <sub>4</sub> )	– 4,0 g/L
Magnesium chloride (MgCl <sub>2</sub> ·6H <sub>2</sub> O)	– 10,78 g/L
Sodium chloride (NaCl)	– 23,5 g/L
Sodium silicate (Na <sub>2</sub> SiO <sub>3</sub> ·9H <sub>2</sub> O)	– 20 mg/L
Sodium bicarbonate (NaHCO <sub>3</sub> )	– 200 mg/L

NOTE 1 A standard marine test medium is used when the solubility or transformation of the metal compound is significantly affected by the high chloride content or other unique chemical characteristics of marine waters and when toxicity data are available on marine species.

NOTE 2 The standard marine test medium should have a salinity of 34 ± 0,5 g/kg and a pH 8,0 ± 0,2.

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**H.3.5.3** Nitric acid (HNO<sub>3</sub>), 1 %, by volume.

**H.3.5.4** Hydrochloric acid (HCl), 1:1.

### H.3.6 Prerequisites

#### H.3.6.1 Test conditions

The following test conditions apply:

a) ambient temperature between 20,0 °C ± 0,2 °C to 25,0 °C ± 0,2 °C;

b) pH range as given in H.3.1.2;

NOTE The pH remains constant (± 0,2 °C) during most tests although some short-term pH variations have been encountered at 100 mg/L loadings of reactive fine powders owing to the inherent properties of the substance in the finely divided state.

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- c) adequate head space in the test vessel to maintain the dissolved oxygen concentration 70 % above its saturation in air (about 8,5 mg/L of oxygen);
- d) reduce chemical and biological contamination as well as evaporation by performing the test in the dark, whenever possible.

### **H.3.6.2 Appropriate pH of the test medium**

**H.3.6.2.1** If no data is available on the appropriate pH, carry out a preliminary screening test (see H.3.6.3.3) to ensure that the test is performed at a pH maximizing transformation/dissolution within the pH range as given in H.3.1.2.

**H.3.6.2.2** Buffering at pH 8 is established by equilibrium with air, in which the concentration of carbon dioxide provides a natural buffering capacity sufficient to maintain the pH within an average of  $\pm 0,2$  pH units over a period of one week. An increase in headspace/liquid ratio can be used to improve the air buffering capacity of the medium.

**H.3.6.2.3** Alternative buffering methods to carbon dioxide may be used if the influence of the applied buffer on the chemical speciation and transformation rate of the dissolved metal fraction would be minimal.

### **H.3.6.3 Reproducibility**

**H.3.6.3.1** For a standard set-up of three replicate test vessels and two replicate samples per test vessel at each sampling time, a constant loading of a substance, tested in a narrow particle size of 37  $\mu\text{m}$  to 44  $\mu\text{m}$  and total surface area range, is anticipated. The within-vessel variation in test results should be less than 10 % and the between-vessel variation should be less than 20 %.

**H.3.6.3.2** A preliminary test is performed to improve reproducibility by adjusting the final test set-up through varying the number of replica test vessels and/or replica samples or further screening of the particles. The preliminary tests also allow for a first evaluation of the transformation rate of the tested substance and can be used to establish the sampling frequency.

**H.3.6.3.3** The preliminary test is carried out as follows:

- a) adjust the pH of the test medium to the desired pH (air buffering or  $\text{CO}_2$  buffering) by agitation for about half an hour to bring the test medium into equilibrium with the buffering atmosphere. Draw at least three samples (10 mL to 15 mL) from the test medium prior to addition of the test substance and use the measured the dissolved metal concentrations as controls and background;
- b) add the metal or metal compound to the test medium at a concentration of 100 mg/L to at least five reaction flasks (see H.3.4.1). Close the flasks with stoppers and agitated the solutions (see H.3.7) at ambient temperature (see H.3.6.1(a)) for a period of 24 h in the dark to reduce chemical and biological contamination. Take triplicate samples with a syringe or a pipette (see H.3.4.6) from each test vessel and separate the solid and solution by filtrating the solution through a filter of pore size 0,2  $\mu\text{m}$  and using a filter of pore size 0,8  $\mu\text{m}$  as pre-filter;
- c) acidify the filtered solutions with 1% nitric acid (see H.3.5.3) and determine the total dissolved metal content by means of atomic absorption spectrometry or ICP spectrometry. Note the average value obtained (see H.3.6.3.1).

### **H.3.7 Agitation methods**

**H.3.7.1** During the transformation/dissolution tests, agitation should be sufficient to maintain the flow of the test medium over the test substance while maintaining the integrity of the surface of the test substance and of any solid reaction product formed during the test. For 1 L of test medium this is accomplished by the use of a radial impeller or a laboratory shaker (see H.3.4.3).

**H.3.7.2** Methods of agitation other than those mentioned in H.3.7.1 may be used, provided that the criteria of surface integrity and homogeneity of the test solution are met.

### **H.3.8 Solid-liquid separation methods**

**H.3.8.1** The choice of a solid-liquid separation method depends on whether soluble metal ions adsorb on filters and whether or not a suspension is generated by the agitation prescribed in H.3.7.

**H.3.8.2** For solids of density greater than 6 g/cm<sup>3</sup> and particle sizes smaller than 8 µm for 50 % of test solution, experience has shown that the gentle agitation methods are unlikely to result in suspensions. A solution free from solids would be obtained by filtering the suspension through a polyethersulfone membrane filter of 25 mm diameter and a pore size of 0,2 µm (as an option, overlain by a 0,8 µm pre-filter). However, if suspensions occur, it might be useful to stop agitation and allow the suspension to settle for about 5 min before filtering.

### **H.3.9 Procedure**

#### **H.3.9.1 Screening test**

**H.3.9.1.1** Clean all glass apparatus by standard laboratory practices and then acid-clean with hydrochloric acid (see H.3.5.4) and subsequently rinse with de-ionised water.

**H.3.9.1.2** Prepare adequate test medium (see H.3.5.1 and H.3.5.2) within a pH range of pH 6 to pH 8,5. Sterilize the test medium by filtration through a membrane filter of pore size 0,2 µm (see H.3.4.4).

**H.3.9.1.3** Transfer the test medium to at least three test flasks of capacity 1 L or 3 L. The volume of the flasks should be sufficient to hold 1 L or 2 L of the test medium without overflow during the agitation.

NOTE The number of flasks depends on the reproducibility obtained during the preliminary test (see H.3.6.3.3).

**H.3.9.1.4** Agitate the test medium for 30 min to bring the test medium into equilibrium with the atmosphere or the buffering system (see H.3.6.2).

**H.3.9.1.5** Measure the pH, the temperature and the dissolved oxygen of the test medium.

**H.3.9.1.6** By means of a syringe or pipette, take duplicate samples of 10 mL or 15 mL from each tests flask. Determine the dissolved metal concentration and use the value as a control and background.

**H.3.9.1.7** Add the metal/metal compound to the test flasks at a loading of 100 mg/L. Stopper the flasks and agitate rapidly and vigorously for 24 h. Measure the pH, temperature and the dissolved oxygen concentration of each flask.

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**H.3.9.1.8** By means of a syringe or pipette, take two to three samples of 10 mL or 15 mL from each tests flask. Filter the samples through a membrane filter of pore size 0,2 µm, acidify the solutions with nitric acid and determine the total dissolved metal content by means of atomic absorption spectrometry or ICP spectrometry.

### **H.3.9.2 Full test — metals and metal compounds**

#### **H.3.9.2.1 Seven-day (short-term) test**

**H.3.9.2.1.1** Prepare adequate test medium (see H.3.5.1 and H.3.5.2) and buffer at pH 6 to pH 8 (see H.3.6.2).

**H.3.9.2.1.2** Add the test substance at loadings of 1mg/L, 10 mg/L and 100 mg/L, respectively, to 1 L or 3 L flasks (the number of flasks depends on the reproducibility as established in H.3.6.3), containing the test medium.

**NOTE** A volume of test medium similar to that of the test solution with no loaded test substance is taken through the same procedure as for the test solution to be used as a control sample (blank test solution).

**H.3.9.2.1.3** Stopper the flasks and agitate as described in H.3.7.

**H.3.9.2.1.4** By means of a syringe or pipette, draw at least two volumes, 10 mL or 15 mL, of the test solution from each flask after agitation of 2 h, 6 h, 1 d, 4 d and 7 d. Measure the temperature, pH and dissolved oxygen concentration of the test solutions at the same time. The maximum total volume taken from the test solutions shall not exceed 20 % of the initial test solution volume.

**H.3.9.2.1.5** Replenish the test medium after the first 24 h with a volume of fresh test medium equal to the volume already drawn and repeat after subsequent samplings.

**H.3.9.2.1.6** Separate the solid and liquid fractions of the test solution in accordance with H.3.8. Acidify the filtrate with 1 mL nitric acid (see H.3.5.3) and determine the dissolved metal content by means of atomic absorption spectrometry or ICP spectrometry.

**H.3.9.2.1.7** Stop the test when the results of three subsequent total dissolved metal concentration do not vary more than 15 %.

#### **H.3.9.2.2 Twenty eight-day (long-term) test**

**H.3.9.2.2.1** Prepare adequate test medium (see H.3.5.1, H.3.5.2 and H.3.6.2) and buffer at pH 5,5 to pH 6.

**H.3.9.2.2.2** Add the test substance at a loading of 1 mg/L to 1 L or 3 L flasks (the number of flasks depends on the reproducibility as established in H.3.6.3).

**NOTE** A volume of test medium similar to that of the test solution with no loaded test substance is taken through the same procedure as for the test solution to be used as a control sample (blank test solution).

**H.3.9.2.2.3** Stopper the flasks and agitate as described in H.3.7.

**H.3.9.2.2.4** By means of a syringe or a pipette, draw at least two volumes, 10 mL or 15 mL, of the test solution from each flask after agitation of 2 h, 6 h, 1 d, 4 d, 7 d, 14 d, 21 d and 28 d. Measure the temperature, pH and dissolved oxygen concentration of each test solution at the same time. The maximum total volume taken from the test solutions shall not exceed 20 % of the initial test solution volume.



**H.3.9.2.2.5** Replenish the test medium after the first 24 h with a volume of fresh test medium equal to the volume already drawn and repeat after subsequent samplings.

**H.3.9.2.2.6** Separate the solid and liquid fractions of the test solution in accordance with H.3.8. Acidify the filtrate with 1 mL nitric acid (see H.3.5.3) and determine the dissolved metal content by means of atomic absorption spectrometry or ICP spectrometry.

**H.3.9.2.2.7** Stop the test when the results of three subsequent total dissolved metal concentration do not vary more than 15 %.

## **H.3.10 Calculations**

### **H.3.10.1 Screening test**

Calculate the mean dissolved metal concentration at 24 h (with confidence intervals).

### **H.3.10.2 Full test**

Plot the dissolved metal concentrations measured during the 7-d (short-term) test or the 28 d (long-term) test versus time and the transformation/dissolution kinetics, as applicable.

## **H.3.11 Test report**

The test report should include (but is not limited to) the following information (see also H.3.3):

- a) identification of the sponsor and testing facility;
- b) description of the tested substance;
- c) description of the reconstituted test medium and metal loadings;
- d) test medium buffering system used and validation of the pH as described in H.3.1.2 and the description of the analytical method;
- e) detailed descriptions of the test apparatus and procedure;
- f) preparation of the standard metal solution;
- g) results of the method validation;
- h) results from the analyses of metal concentrations, pH, temperature, oxygen;
- i) dates of tests and analyses at the various time intervals;
- j) mean dissolved metal concentration at different time intervals (with confidence intervals);
- k) transformation curves (total dissolved metal as a function of time);
- l) results from transformation/dissolution kinetics, if determined;
- m) estimated reaction kinetic equation, if determined;
- n) deviations from the study plan if any and reasons;
- o) any circumstances that may have affected the results; and
- p) reference to the records and raw data.

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# **Annex I**

## **RELEVANT SOUTH AFRICAN REGULATIONS AND STATUTORY PROVISIONS**

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## **Annex I** (informative)

### **Relevant South African regulations and statutory provisions**

Basic Conditions of Employment Act, 1997 (Act No. 75 of 1997).

Environment Conservation Act, 1989 (Act No. 73 of 1989).

Environment Conservation Act Extension Act, 1996 (Act No. 100 of 1996).

Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) (as amended).

Fire Brigade Services Act, 1987 (Act No. 99 of 1987).

Hazardous Substances Act, 1973 (Act No. 15 of 1973).

Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965).

Medicines and Related Substances Control Amendment Act, 1997 (Act No. 90 of 1997).

National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004).

National Environmental Management Act, 1998 (Act No. 107 of 1998).

National Environmental Management Amendment Act, 2003 (Act No. 46 of 2003).

National Environmental Management: Protected Areas Act, 2003 (Act No. 57 of 2003).

National Environment Management: Air Quality Act, 2004 (Act No. 39 of 2004).

National Road Traffic Act, 1996 (Act No. 93 of 1996).

National Road Traffic Amendment Act, 2003 (Act No. 20 of 2003).

National Road Traffic Regulations, 2000 of the National Road Traffic Act, 1996 (Act No. 93 of 1996).

National Water Act, 1998 (Act No. 36 of 1998).

Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

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# **Annex J**

## **INTERNATIONALLY ACCEPTED TEST METHODS FOR HEALTH AND ENVIRONMENTAL HAZARDS**

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## **Annex J**

(normative)

### **Internationally accepted test methods for health and environmental hazards**

#### **Health hazards**

OECD Test Guideline 414, *Development of toxicity testing*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 415, *Method for one-generation toxicity testing*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 416, *Method for two-generation toxicity testing*. OECD Guidelines for the testing of chemicals. Paris, France. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 421, *Reproduction/developmental toxicity screening test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 422, *Combined repeated-dose toxicity study reproduction/developmental toxicity screening test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 430, *In vitro skin corrosion: Transcutaneous electrical resistant test (TER)*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 431, *In vitro skin corrosion: Human skin model test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 471, *Bacterial reverse mutation test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 473, *In vitro mammalian chromosome aberration test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 474, *Mammalian erythrocyte micronucleus test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 475, *Mammalian bone marrow chromosome aberration test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 476, *In vitro mammalian cell gene test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 483, *Mammalian spermatogonial chromosome aberration test*. OECD Guidelines for the testing of chemicals. Paris, France.

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OECD Test Guideline 484, *Mouse spot test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 485, *Mouse heritable translocation assay*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 486, *Liver unscheduled DNA Synthesis (USD) in vitro*. OECD Guidelines for the testing of chemicals. Paris, France.

### **Aquatic toxicity**

OECD Test Guideline 201 (1984), *Algae – Growth inhibition test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 202 (1984), *Daphnia sp. acute immobilisation test and reproduction test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 203 (1992), *Fish, acute toxicity test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 204 (1984), *Fish, prolonged toxicity test: 14-day study*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 210 (1992), *Fish, early-life stage toxicity test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 211 (1998), *Daphnia magna reproduction test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 212 (1998), *Fish, short-term toxicity test on embryo and sac-fry stages*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 215 (2000), *Fish, juvenile growth test*. OECD Guidelines for the testing of chemicals. Paris, France.

OECD Test Guideline 221 (1992), *Lemna sp. growth inhibition test*. OECD Guidelines for the testing of chemicals. Paris, France.

### **Biotic and abiotic degradation**

OECD Test Guideline 111 (1981), *Hydrolysis as a function of pH*. OECD Guidelines for testing chemicals. Paris, France.

OECD Test Guideline 209 (1984), *Activated sludge, respiration inhibition test*. OECD Guidelines for testing chemicals. Paris, France.

OECD Test Guideline 301 (1992), *Ready biodegradability*. OECD Guidelines for testing chemicals. Paris, France.

OECD Test Guideline 302A (1981), *Inherent biodegradability: Modified SCAS test*. OECD Guidelines for testing chemicals. Paris, France.

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OECD Test Guideline 302B (1992), *Zahn-Wellens/EMPA test*. OECD Guidelines for testing chemicals. Paris, France

OECD Test Guideline 302C (1981), *Inherent biodegradability: Modified MITI test (II)*. OECD Guidelines for testing chemicals. Paris, France.

OECD Test Guideline 303A (1981), *Simulation test – aerobic sewage treatment: Coupled units test*. OECD Guidelines for testing chemicals. Paris, France.

OECD Test Guideline 304A (1981), *Inherent biodegradability in soil*. OECD Guidelines for testing chemicals. Paris, France.

OECD Test Guideline 306 (1992), *Biodegradability in seawater*. OECD Guidelines for testing chemicals. Paris, France.

OECD (1995), *Detailed review paper on biodegradability testing*. OECD Environmental Monograph No. 98. Paris, France.

OECD (1998), *Aerobic and anaerobic transformation in aquatic sediment systems*. Paris, France.

OECD (October 1999), *Aerobic and anaerobic transformation in soil*. Final text of a draft proposal for a new guideline. Paris France.

OECD (May 2000), *Simulation test – Aerobic Transformation in Surface Water*. Draft proposal for a new guideline. Paris, France.

ISO 9408, *Water quality – Evaluation in an aqueous medium of the "ultimate" biodegradability of organic compounds – Method by determining the oxygen demand in a closed respirometer*.

ISO 9439, *Water quality – Evaluation in an aqueous medium of the "ultimate" biodegradability of organic compounds – Method by analysis of released carbon dioxide*.

ISO 9509, *Water quality – Method for assessing the inhibition of nitrification of activated sludge micro-organisms by chemicals and wastewaters*.

ISO 9887, *Water quality – Evaluation of the aerobic biodegradability of organic compounds in an aqueous medium – Semicontinuous activated sludge method (SCAS)*.

ISO 9888, *Water quality – Evaluation of the aerobic biodegradability of organic compounds in an aqueous medium – Static test (Zahn-Wellens method)*.

ISO 10707, *Water quality – Evaluation in an aqueous medium of the "ultimate" biodegradability of organic compounds – Method by analysis of biochemical oxygen demand (closed bottle test)*.

ISO 11348, *Water quality – Determination of the inhibitory effect of water samples on the light emission of 'Vibrio fischeri' (Luminescent bacteria test)*.

ISO 11733, *Water quality – Evaluation of the elimination and biodegradability of organic compounds in an aqueous medium – Activated sludge simulation test*.

ISO 11734, *Water quality – Evaluation of the "ultimate" anaerobic biodegradability of organic compounds in digested sludge – Method by measurement of the biogas production*.

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ISO 14592, *Water quality – Evaluation of the aerobic biodegradability of organic compounds at low concentrations in water*. Part 1: *Shake flask batch test with surface water or surface water/sediment suspensions*.

### **Bioaccumulation**

OECD Test Guideline 107 (1995), *Partition coefficient (n-octanol/water): Shake flask method*. OECD Guidelines for testing of chemicals. Paris, France.

OECD Test Guideline 117 (1989), *Partition coefficient (n-octanol/water) – High performance liquid chromatography (HPLC) method*. OECD Guidelines for testing of chemicals. Paris, France.

OECD Test Guideline 305, (1996), *Bioconcentration: Flow-through fish test*. OECD Guidelines for testing of chemicals. Paris, France.

OECD 305 A-E, (1981), *Bioaccumulation*. OECD Guidelines for testing of chemicals. Paris, France.

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